

**Recommendation of the European Chemicals Agency
of 10 November 2016
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/EC¹, and in particular Article 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation, as amended by Decision ED/49/2014²,

Having regard to the opinion of ECHA's Member State Committee of 13 September 2016³,

Whereas:

- (1) This Recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV to the REACH Regulation.
- (2) Pursuant to Article 58(3) of the REACH Regulation, ECHA is required 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 pursuant to Article 58(3) of the REACH Regulation⁴, ECHA had prioritised the following 11 substances from the Candidate List for its draft Recommendation of substances to be included in Annex XIV⁵:

¹ OJ L 396, 30.12.2006, p 1

² <http://echa.europa.eu/web/guest/candidate-list-table>

³ https://echa.europa.eu/documents/10162/13576/msc_opinion_draft_7th_axiv_recommendation_en.pdf

⁴ http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

⁵ https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf as published on ECHA's website on 18 November 2015

Draft recommendation		
#	Substance name	EC
1	<i>1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear</i>	271-093-5
2	<i>Dihexyl phthalate</i>	201-559-5
3	<i>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)</i>	201-604-9 236-086-3 238-009-9
4	<i>Hexahydromethylphthalic 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-stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry] (MHPA)</i>	247-094-1 243-072-0 256-356-4 260-566-1
5	<i>Trixylyl phosphate</i>	246-677-8
6	<i>Sodium perborate; perboric acid, sodium salt</i>	239-172-9 234-390-0
7	<i>Sodium peroxometaborate</i>	231-556-4
8	<i>Orange lead (lead tetroxide)</i>	215-235-6
9	<i>Lead monoxide (lead oxide)</i>	215-267-0
10	<i>Pentalead tetraoxide sulphate</i>	235-067-7
11	<i>Tetralead trioxide sulphate</i>	235-380-9

- (4) In accordance with Article 58(4) of the REACH Regulation, ECHA published on its website on 18 November 2015 the draft recommendation and invited all interested parties to submit comments by 18 February 2016. ECHA has analysed and prepared responses to comments received and will provide them to the Commission as part of the recommendation documents. Public versions will be made available on ECHA's website⁶.
- (5) In accordance with Article 58(3), 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 public consultation and in updated registrations and updated the priority assessment of the substances by applying the prioritisation approach⁴.
- (7) The priority of HHPA decreased in light of the new information described above. In particular, HHPA now has a similar priority to other substances that were not considered for this recommendation. It would therefore be appropriate to assess the priority to include HHPA in Annex XIV together with those substances. Recognising also that there is still a substantial number of substances recommended by ECHA that have not yet been included in Annex XIV by the Commission and taking account of the capacity to manage authorisation applications, ECHA considers that it is justified to recommend less substances this time. Reflecting on the overall functioning and predictability of the authorisation process, ECHA decided to leave out HHPA and MHPA (grouped together) from this recommendation.

⁶ See responses given under:
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations>

- (8) ECHA recommends the following 9 substances for inclusion in Annex XIV:

Recommendation		
#	Substance name	EC
1	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5
2	Dihexyl phthalate	201-559-5
3	Trixylyl phosphate	246-677-8
4	Sodium perborate; perboric acid, sodium salt	239-172-9 234-390-0
5	Sodium peroxometaborate	231-556-4
6	Orange lead (lead tetroxide)	215-235-6
7	Lead monoxide (lead oxide)	215-267-0
8	Pentalead tetraoxide sulphate	235-067-7
9	Tetralead trioxide sulphate	235-380-9

- (9) ECHA is required by Article 58(1) 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"); the date referred to in Article 58(1)(c)(i) of the REACH Regulation from which the placing of the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"); the 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.
- (10) Using the approach developed to support determining the Annex XIV entries of prioritised substances⁷ ECHA has determined the specific Annex XIV entries for each of the above listed substances.
- (11) In order to identify the substances pursuant to Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances and, where applicable, their EC numbers and CAS numbers.
- (12) 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 public consultation provide information that would support the recommendation of longer periods.
- (13) The latest application dates have been set having regard to ECHA's capacity to handle applications in the time provided for, in accordance with Art. 58(3) of the REACH Regulation, over a period of 9 months (18, 21, 24 or 27 months from entry

⁷ https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

into force) to distribute the workload in the authorisation application and decision phase more evenly.

- (14) The information available for the recommended substances, including the comments received during the public consultation, which took place from 18 November 2015 to 18 February 2016, does not provide information that would justify for the upfront definition of review periods for any uses of the substances in accordance with Article 58(1)(d) of the REACH Regulation.
- (15) 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.
- (16) ECHA has received during the public consultation, which took place from 18 November 2015 to 18 February 2016, comments requesting exemptions of uses. Based on its assessment of these exemption requests⁶, ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) and Article 58(2) of the REACH Regulation.
- (17) 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 public consultation, does not provide grounds to recommend exemptions from the authorisation requirement for PPORD on the basis of Article 56(3) of the REACH Regulation.

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	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
2	Dihexyl phthalate	201-559-5	84-75-3	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
3	Trixylyl phosphate	246-677-8	25155-23-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
4	Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	-	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
5	Sodium peroxometaborate	231-556-4	7632-04-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None

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
6	Pentalead tetraoxide sulphate	235-067-7	12065-90-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None
7	Tetralead trioxide sulphate	235-380-9	12202-17-4	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None
8	Orange lead (lead tetroxide)	215-235-6	1314-41-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 27 months	Latest application date plus 18 months	None	None	None
9	Lead monoxide (lead oxide)	215-267-0	1317-36-8	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 27 months	Latest application date plus 18 months	None	None	None

* 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 determination of LADs is based on the "General approach for the preparation of draft Annex XIV entries". 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.

Done at Helsinki, 10 November 2016
For the European Chemicals Agency,
(e-signed)⁸

Jukka Malm⁹
Deputy Executive Director

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.

⁹ Mandated to sign this decision pursuant to the decision of the Executive Director ED/20/2015 delegating the power to sign the submissions to the European Commission of the final Agency recommendation of priority substances to be included in Annex XIV under Article 58(3) of the REACH Regulation to Jukka Malm, Deputy Executive Director.

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 exempted from authorisation. It also reflects how ECHA has taken account of the comments received in the public 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 public 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 public 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 any of the substances at the link: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations>

- General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) (10 February 2014);
- General Approach for the preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV (18 November 2015);
- Priority assessment results of the Candidate List substances included in the Candidate List by June 2014 (18 November 2015);
- Draft 7th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation' (18 November 2015);

- Updated priority assessment results of the substances included in ECHA's 7th draft recommendation (10 November 2016);
- Opinion of the Member State Committee on the 7th draft recommendation of the priority substances and Annex XIV entries (Adopted on 13 September 2016).

[see Table 1 on next page]

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	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (271-093-5)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_benzenedicarboxylic_acid_dihexyl_ester_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_benzenedicarboxylic_acid_dihexyl_ester_en.rtf	https://echa.europa.eu/documents/10162/13640/7th_recom_response_doc_phthalates_en.pdf
2	Dihexyl phthalate (201-559-5)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_dihexyl_phthalate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_dihexyl_phthalate_en.rtf	
3	Trixylyl phosphate (246-677-8)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_trixylyl_phosphate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_trixylyl_phosphate_en.rtf	https://echa.europa.eu/documents/10162/13640/7th_recom_response_doc_trixylyl_phosphate_en.pdf
4	Sodium perborate; perboric acid, sodium salt (239-172-9; 234-390-0)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_sodium_perborate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_sodium_perborate_en.rtf	https://echa.europa.eu/documents/10162/13640/7th_recom_response_doc_perborates_en.pdf
5	Sodium peroxometaborate (231-556-4)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_sodium_peroxometaborate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_sodium_peroxometaborate_en.rtf	
6	Pentalead tetraoxide sulphate (235-067-7)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_pentalead_tetraoxide_sulphate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_comref_pentalead_tetraoxide_sulphate_en.rtf	

7	Tetralead trioxide sulphate (235-380-9)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_tetralead_trioxide_sulphate_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_cmref_tetralead_trioxide_sulphate_en.rtf	https://echa.europa.eu/documents/10162/13640/7th_recom_repdoc_leads_en.pdf
8	Orange lead (lead tetroxide) (215-235-6)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_orange_lead_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_cmref_orange_lead_en.rtf	
9	Lead monoxide (lead oxide) (215-267-0)	https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_lead_monoxide_en.pdf	https://echa.europa.eu/documents/10162/13640/7th_recom_cmref_lead_monoxide_en.rtf	