

**Recommendation of the European Chemicals Agency  
of 12 April 2023  
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/EC<sup>1</sup>, and in particular Article 58 thereof,

Having regard to the version of the Candidate List of Substances of Very High Concern for authorisation as last amended by Decision D(2021)4569-DC on 8 July 2021<sup>2</sup>,

Having regard to the opinion of ECHA's Member State Committee of 8 February 2023<sup>3</sup>,

Whereas:

- (1) This Recommendation aims to assist the Commission in taking its decision under Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV to the REACH Regulation.
- (2) Article 58(3) of the REACH Regulation requires ECHA 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 under Article 58(3) of the REACH Regulation<sup>3</sup>, ECHA prioritised the following eight substances from the Candidate List for its draft Recommendation of substances to be included in Annex XIV<sup>3</sup>:

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<sup>1</sup> OJ L 396, 30.12.2006, p 1

<sup>2</sup> <https://www.echa.europa.eu/candidate-list-table>

Note that this is a link that also includes amendments made to the Candidate List after 8 July 2021. These amendments have not been considered in this recommendation.

<sup>3</sup> [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#)

<b>Draft recommendation</b>		
<b>#</b>	<b>Substance name</b>	<b>EC</b>
1	<i>Orthoboric acid, sodium salt</i>	237-560-2
2	<i>Diisohexyl phthalate</i>	276-090-2
3	<i>2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers</i>	-
4	<i>Ethylenediamine</i>	203-468-6
5	<i>Glutaral</i>	203-856-5
6	<i>2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one</i>	400-600-6
7	<i>2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone</i>	404-360-3
8	<i>Lead</i>	231-100-4

- (4) Under Article 58(4) of the REACH Regulation ECHA published on its website on 2 February 2022 the draft Recommendation and invited all interested parties to submit comments by 2 May 2022. ECHA has analysed and prepared responses to comments received and they are provided to the Commission as part of the recommendation documents. Public versions are made available on ECHA's website<sup>3</sup>.
- (5) Article 58(3) of the REACH Regulation provides that 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 consultation and in updated registrations and updated the priority assessment of the substances by applying the prioritisation approach<sup>3</sup>.
- (7) ECHA recommends the following eight substances for inclusion in Annex XIV:

<b>Recommendation</b>		
<b>#</b>	<b>Substance name</b>	<b>EC</b>
1	Orthoboric acid, sodium salt	237-560-2
2	Diisohexyl phthalate	276-090-2
3	2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	-
4	Ethylenediamine	203-468-6
5	Glutaral	203-856-5
6	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6
7	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3
8	Lead	231-100-4

- (8) ECHA is required under Articles 58(1) and (3) 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 on 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.

- (9) Using the approach developed to support determining the Annex XIV entries of prioritised substances<sup>3</sup>, ECHA has determined the specific Annex XIV entries for each of the above listed substances.
- (10) In order to identify the substances under Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances and, where applicable, their EC numbers and CAS numbers.
- (11) 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 consultation provide information that would support the recommendation of longer periods.
- (12) For lead (EC 231-100-4), the latest application date has been set having regard to ECHA's capacity to handle applications in the time provided for, under Article 58(3) of the REACH Regulation. On this basis, it is recommended to set the latest application date for lead to at least 36 months from the date of inclusion of the substance in Annex XIV.
- (13) Certain uses of lead fall within the scope of Directive 2011/65/EU<sup>4</sup>, Directive 2000/53/EC<sup>5</sup> and Directive (EU) 2020/2184<sup>6</sup>. In addition, some uses of lead may in the future fall within the scope of the proposed Regulation of the European Parliament and of the Council concerning batteries and waste batteries<sup>7</sup>. Should the Commission decide not to exempt those uses under Article 58(2) of the REACH Regulation, ECHA invites the European Commission to consider defining additional longer latest application date(s) and sunset dates(s) for those uses. This would ensure that the workload in the authorisation application and decision phase is distributed more evenly.
- (14) For the remaining substances of the recommendation, the latest application dates have been set having regard to ECHA's capacity to handle applications in the time provided for, under Article 58(3) of the REACH Regulation, over a period of 6 months (18, 21, or 24 months from the date these substances have been included in Annex XIV) to distribute the workload in the authorisation application and decision phase more evenly.
- (15) The information available for the recommended substances, including the comments received during the consultation, does not provide information that

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<sup>4</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (OJ L 418, 24.11.2021, p. 6).

<sup>5</sup> Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34).

<sup>6</sup> Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

<sup>7</sup> Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (COM/2020/798 final).

would justify for the upfront definition of review periods for any uses of the substances under Article 58(1)(d) of the REACH Regulation.

- (16) Article 58(1)(e) in conjunction with Article 58(2) of the REACH Regulation 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.
- (17) ECHA has received during the consultation comments requesting exemptions of some uses. Based on its assessment of these exemption requests<sup>8</sup>, ECHA does not recommend any exemptions from the authorisation requirement under Article 58(1)(e) and Article 58(2) of the REACH Regulation.
- (18) 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 consultation, does not provide grounds to recommend exemptions from the authorisation requirement for PPORD under Article 56(3) of the REACH Regulation.

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<sup>8</sup> See [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#).

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	Orthoboric acid, sodium salt	237-560-2	13840-56-7	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>18</u> months	Latest application date plus 18 months	None	None	None
2	Diisohexyl phthalate	276-090-2	71850-09-4	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>18</u> months	Latest application date plus 18 months	None	None	None
3	2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	-	-	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>18</u> months	Latest application date plus 18 months	None	None	None
4	Ethylenediamine	203-468-6	107-15-3	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus <u>18</u> months	Latest application date plus 18 months	None	None	None
5	Glutaral	203-856-5	111-30-8	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus <u>21</u> months	Latest application date plus 18 months	None	None	None
6	2-methyl-1-(4-methyl thiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>24</u> months	Latest application date plus 18 months	None	None	None
7	2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone	404-360-3	119313-12-1	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>24</u> months	Latest application date plus 18 months	None	None	None
8	Lead	231-100-4	7439-92-1	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus <u>at least 36</u> months ( <sup>1)</sup> )	Latest application date plus 18 months ( <sup>1)</sup> )	None	None	None

Notes to the Draft Annex XIV entries table

- \* 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 latest application dates were determined on the basis of the General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV<sup>8</sup> and as further specified in the practical implementation document<sup>9</sup>. 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.
- <sup>1)</sup> As outlined in Article 58(3) of the REACH Regulation, when setting latest application dates, ECHA also needs to consider the Agency's capacity to handle applications in the time provided for. In case uses that are within the scope of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2000/53/EC on end-of life vehicles, and Directive (EU) 2020/2184 on the quality of water intended for human consumption, (including upstream uses) are not exempted from the Authorisation requirement under Art 58(2) of the REACH Regulation, the Commission may consider defining additional longer latest application date(s) and Sunset dates(s) for such uses, with the aim to spread the workload for ECHA, its Committees and Commission when dealing with authorisation applications, and to facilitate regulatory coherence of decisions taken under those specific legislative frameworks and REACH. Similar, considerations may apply for uses of lead in batteries should the proposed Regulation concerning batteries and waste batteries be adopted before the Commission amends Annex XIV.

Done at Helsinki, 12 April 2023  
For the European Chemicals Agency,

*(e-signed)*<sup>9</sup>

Ofelia Bercaru  
Director of Prioritisation and Integration

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<sup>9</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision approval process.

## Annex I - Reasons for the recommendation to include the prioritised substances in Annex XIV

This Annex lists all documents relevant for this recommendation, which can be found under the substance specific entries of the [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](https://echa.europa.eu):

- **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 of uses exempted from authorisation. It also reflects how ECHA has taken account of the comments received in the 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 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 consultation. Response documents are developed per substance or group of substances.

Additional documents relevant for the recommendation are:

- General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) (10 February 2014, editorially updated 5 March 2020);
- General Approach for the preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV (18 November 2015, editorially updated 5 March 2020);
- Setting LADs - Practical implementation of the Annex XIV entries approach (2 March 2017, editorially updated 5 March 2020);
- Priority assessment results of the Candidate List substances included in the Candidate List by July 2019 (5 March 2020);
- Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (2 February 2022);
- Updated priority assessment results of the substances included in ECHA's 11th draft recommendation (12 April 2023);
- Opinion of the Member State Committee on the 11th draft recommendation of the priority substances and Annex XIV entries (Adopted on 8 February 2023)