

12 April 2023

Background document for orthoboric acid, sodium salt

Document developed in the context of ECHA's eleventh recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of orthoboric acid, sodium salt in the Authorisation List or in the registration dossiers¹ as well as the MSC opinion² were taken into consideration when finalising the recommendation and are reflected in the present final background document.

For orthoboric acid, sodium salt no comments were received in the consultation.

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¹ As of the last day of the consultation, i.e. 2 May 2022.

² Opinion of the Member State Committee on the draft eleventh recommendation of the priority substances to be included in Annex XIV, adopted on 8 February 2023.

1. Identity of the substance

Identity of the substance as provided in the Candidate List³:

Name: orthoboric acid, sodium salt
EC Number: 237-560-2
CAS Number: 13840-56-7

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation (ECHA, 2020). Results of the prioritisation of all substances included in the Candidate List by July 2021 and not yet recommended or included in Annex XIV of the REACH Regulation are available in ECHA (2022a).

The prioritisation results of the substances included in the draft 11th recommendation have been updated as necessary after the consultation. The updated results are available at in ECHA (2023).

2.1. Intrinsic properties

Orthoboric acid, sodium salt was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360FD (“May damage fertility. May damage the unborn child”) and was therefore included in the Candidate List for authorisation on 8 July 2021, following ECHA’s decision D(2021)4569-DC.

2.2. Volume used in the scope of authorisation

There are no registrations for orthoboric acid, sodium salt under Regulation (EC) No 1907/2006 (ECHA, 2022b).

2.3. Wide-dispersiveness of uses

There are no registrations for orthoboric acid, sodium salt under Regulation (EC) No 1907/2006 (ECHA, 2022b).

2.4. Further considerations for priority setting

Based on structural similarities orthoboric acid, sodium salt might be used as a substitute for other borates that were already recommended in the 6th and 10th Annex XIV recommendations. There are indications on the potential for using the substances in the same type of applications (e.g. corrosion inhibitor).

³ For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

2.5. Conclusion

Orthoboric acid, sodium salt is recommended for inclusion in Annex XIV on the basis of grouping considerations.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD): Date of inclusion in Annex XIV plus **18 months**

Sunset date: 18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances recommended can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

The substance has not been registered, indicating that it is either currently not used in the EU, or if so (i.e. in tonnages below 1 t/y) the number of different uses can be assumed to be low. Consequently, the time needed to prepare an application for authorisation is assumed to be lower when compared with other substances in this recommendation round.

During the consultation no comments were received that challenged the proposed transitional arrangements.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for orthoboric acid, sodium salt.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods for uses of orthoboric acid, sodium salt.**

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for uses of orthoboric acid, sodium salt on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH

Regulation.

During the consultation ECHA did not receive comments requesting exemptions for uses of orthoboric acid, sodium salt.

ECHA therefore **does not recommend exemptions for uses of orthoboric acid, sodium salt** on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of orthoboric acid, sodium salt for PPORD.

During the consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the consultation.

ECHA therefore **does not recommend exempting any use of orthoboric acid, sodium salt for PPORD** from authorisation.

4. References

ECHA (2015): ECHA's 6th recommendation. 1 July 2015.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance boric acid (EC 233-139-2), disodium tetraborate, anhydrous (EC 215-540-4)

- Background document for boric acid. Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV.
- Background document for disodium tetraborate, anhydrous. Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV.

ECHA (2020): Agreed and applied approaches. 5 March 2020.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance orthoboric acid, sodium salt (EC 237-560-2)

- Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.
- Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.
- Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2021): [Registry of SVHC intentions until outcome - ECHA \(europa.eu\)](#), filter by substance orthoboric acid, sodium salt (EC 237-560-2)

- Annex XV report. Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance Name: Orthoboric acid, sodium salt, EC Number: 237-560-2, CAS Number: 13840-56-7.

ECHA (2022a): ECHA's 11th draft recommendation. 2 February 2022.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance orthoboric acid, sodium salt (EC 237-560-2)

- Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2021 and not yet recommended for inclusion in Annex XIV.
- Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation).

ECHA (2022b): Orthoboric acid, sodium salt. ECHA's dissemination website on registered substances. Accessed on 2 May 2022.

<https://echa.europa.eu/search-for-chemicals>

ECHA (2023): ECHA's final 11th recommendation. 12 April 2023.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance orthoboric acid, sodium salt (EC 237-560-2)

- Updated priority assessment results of the substances included in the draft 11th recommendation for inclusion in Annex XIV. 12 April 2023.
- 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).

Annex I: Further information on uses

1. Basis for grouping considerations

Orthoboric acid, sodium salt is a boron compound and structurally similar to other borates recommended in the 6th and 10th Annex XIV recommendations (see Section 2.4). According to registration information as described in the related background documentation (ECHA, 2015), boric acid and disodium tetraborate, anhydrous can be used as corrosion inhibitor. The same use is described for orthoboric acid, sodium salt in the SPIN database (ECHA, 2021). The Annex XV SVHC report (ECHA, 2021) concludes that there is a potential risk for regrettable substitution with the closely related sodium borates already included in the Candidate List.

Additionally, orthoboric acid, sodium salt could be used as a source of boron. Boron is an essential micronutrient required for crop nutrition. Boron is applied as straight fertilisers or added in small quantities to NPK (nitrogenphosphorus-potassium) fertilisers or in liquid specialties for foliar or soil application (ECHA, 2015).

2. Structure and complexity of supply chains

The following assumptions are made to allocate the substance to a specific LAD slot.

Orthoboric acid, sodium salt is not registered and appears to have no uses in the scope of authorisation.