2 February 2022

Draft 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 dossiers (as of the last day of the consultation, i.e. 2 May 2022) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

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[2]. 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 is available at https://echa.europa.eu/documents/10162/17232/prior_results_cl_subst_february_2022_en.pdf.

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 (REACH)[3].

2.3. Wide-dispersiveness of uses

There are no registrations for orthoboric acid, sodium salt under Regulation (EC) No 1907/2006 (REACH)[3].

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).

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf
[3] As of 1 August 2021

2.5. Conclusion

Conclusion
Orthoboric acid, sodium salt is proposed to be prioritised 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, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[4] and the criteria described in the implementation document[5]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in section 2 of Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 11th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for orthoboric acid, sodium salt.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all

[4] General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/
[5] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to 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.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[6]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[7], there is no need to propose an additional specific exemption.

[6] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/17232/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/17232/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[7] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf

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

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of orthoboric acid, sodium salt for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for orthoboric acid, sodium salt[8].

[8] As of 1 August 2021

4. References

Annex XV SVHC report (2021): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Orthoboric acid, sodium salt. Submitted by Sweden, March 2021.

https://www.echa.europa.eu/documents/10162/b4629148-2a72-ca60-a659-07a0d84c3259

ECHA (2015a): Background document for boric acid. Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV. 1 July 2015.

https://echa.europa.eu/documents/10162/df9cfcf1-9c94-4d05-87cf-46dc1c5f3dfd

ECHA (2015b): Background document for disodium tetraborate, anhydrous. Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV. 1 July 2015.

https://echa.europa.eu/documents/10162/d8e46856-eb89-4b45-9d10-8fbd04e08ebf

ECHA (2021): Orthoboric acid, sodium salt. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

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

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 a, b), 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 (see Annex XV SVHC report, 2021). The Annex XV SVHC report (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 2015a, b).

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 appear to have no uses in the scope of authorisation.