

COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

Disclaimer: Comments provided during the consultation are made available as submitted by the commenting parties. It was the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern.

Substance name: Orthoboric acid, sodium salt
 CAS number: 13840-56-7
 EC number: 237-560-2

The substances are proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: Toxic for reproduction (Article 57c)

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5472 2021/04/21	Germany, Member State	The German CA has assessed the SVHC dossier on orthoboric acid, sodium salt and supports the conclusion that an SVHC identification is warranted.	Thank you for your support.

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5462 2021/04/16	Health and Environment Alliance (HEAL),	We thank the Swedish Competent Authority for its proposal to identify orthoboric acid, sodium salts, as a substance of very high concern (SVHC) under REACH article 57(c) - toxic for reproduction - which we fully support.	Thank you for your support.

	International NGO, Belgium	Because the substance is already covered by a CLP classification entry as toxic for reproduction category 1B, we consider this SVHC identification proposal as unequivocal.	
5463 2021/04/17	CHEM Trust Europe, National NGO, Germany	CHEM Trust supports the inclusion of orthoboric acid, sodium salt in in the REACH candidate list owing to their classification as reprotoxicant 1B which fulfills the criterion of article 57 c).	Thank you for your support.
5472 2021/04/21	Germany, Member State	On page 5 of the report it is described that "Other identifiers for orthoboric acid, sodium salt as well as identifiers for hydrated forms of the substance are also within the scope of the entry" and several examples are given. For „boric acid (H3BO3), sodium salt, hydrate, CAS 25747-83-5 (molecular formula BH3O3.xH2OxNa)" the CAS number could not be found in the ECHA database and other databases. Please check.	Thank you for your comment. CAS 25747-83-5 (molecular formula BH3O3.xH2OxNa) has been confirmed by a CAS registry number search in the STN database.
5487 2021/04/22	ANSES, National Authority, France	The harmonised classification Repro 1B-H360FD of this substance fulfils the criteria to identify the substance as an SVHC under article 57(c) and the SVHC identification is supported.	Thank you for your support.
5494 2021/04/22	Norway, Member State	The Norwegian CA supports that orthoboric acid, sodium salt should be identified as a substance of very high concern and should be included in the Candidate List.	Thank you for your support.
5508 2021/04/22	Netherlands, Member State	NL supports the proposal to include Orthoboric acid, sodium salt in the candidate list of SVHC in accordance with Article 57(c) of Regulation (EC) 1907/2006 (REACH) given the reproductive toxicity properties.	Thank you for your support and your comments.

		<p>Considering that the toxic properties are related to Orthoboric acid and not to the sodium cation, we would suggest to include all alkali salt of Orthoboric acid in the candidate list of SVHC in accordance with Article 57(c) of Regulation (EC) 1907/2006 (REACH) given the reproductive toxicity properties, in order to regulate them in the same way as Orthoboric acid, sodium salt to avoid regrettable substitution and to protect human health.</p> <p>This could also be done in a separate activity in which the candidate list is also extended for the alkali salt of the other borates already on the candidate list.</p>	<p>There is ongoing work on regulating inorganic borates. These activities are at different stages and we will consider your comments in our future work.</p>
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PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
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