

Annex XV report

PROPOSAL FOR IDENTIFICATION OF SUBSTANCES 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

Submitted by: Sweden

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PROPOSAL FOR IDENTIFICATION OF SUBSTANCES 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

- The substances covered by this (generic) entry are proposed to be identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to their classification in the hazard class toxic for reproduction category 1B².

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Orthoboric acid, sodium salt is covered by index number 005-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and is classified in the hazard class toxic for reproduction category 1B (H360FD¹).

Therefore, the classification of the substances covered by this (generic) entry in Regulation (EC) No 1272/2008 shows that they meet the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? No

¹ H360FD: 'May damage fertility. May damage the unborn child.'

PART I

Justification

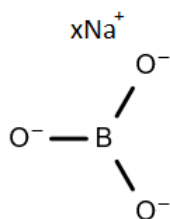
1. Identity of the substances and physical and chemical properties

1.1 Name and other identifiers of the substances

Table 1: Substance identity

EC number:	237-560-2
EC name:	Orthoboric acid, sodium salt
CAS number (in the EC inventory):	13840-56-7
CAS number: Deleted CAS numbers:	13840-56-7
CAS name:	Boric acid (H ₃ BO ₃), sodium salt (1:?)
IUPAC name:	Orthoboric acid, sodium salt
Index number in Annex VI of the CLP Regulation	005-011-00-4
Molecular formula:	BH ₃ O ₃ .xNa
Molecular weight range:	-
Synonyms:	-

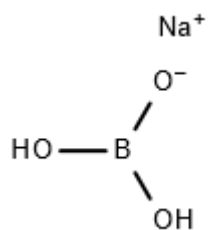
Structural formula:



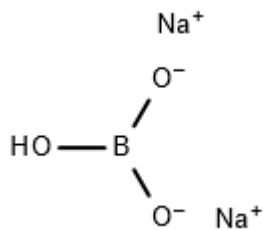
Other identifiers for orthoboric acid, sodium salt as well as identifiers for hydrated forms of the substance are also within the scope of the entry: *e.g.* boric acid, sodium salt, EC 215-604-1, CAS 1333-73-9 (molecular formula BH₃O₃xNa) and boric acid (H₃BO₃), sodium salt, hydrate, CAS 25747-83-5 (molecular formula BH₃O₃.xH₂OxNa).

The SVHC entry of orthoboric acid, sodium salt does not specify the exact ratio of sodium ions to borate. Substances with fixed ratios are also covered by this entry: *e.g.* boric acid (H₃BO₃), sodium salt (1:1), CAS 14890-53-0; boric acid (H₃BO₃), disodium salt, CAS 22454-04-2, and trisodium orthoborate, EC 238-253-6, CAS 14312-40-4.

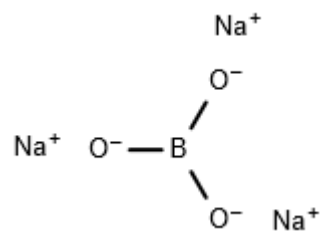
Structural formulas of sodium salts of boric acid with fixed x:



CAS 14890-53-0



CAS 22454-04-2



EC 238-253-6, CAS 14312-40-4

1.2 Composition of the substances

Name: Orthoboric acid, sodium salt

Description: inorganic

Substance type: not specified

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (c) of REACH.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (c) of REACH.

1.5 Physicochemical properties

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (c) of REACH.

2. Harmonised classification and labelling

Orthoboric acid, sodium salt is covered by Index number 005-011-00-4 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
005-011-00-4	orthoboric acid, sodium salt	237-560-2	13840-56-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD : C ≥4,5 %	

3. Environmental fate properties

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (c) of REACH.

4. Human health hazard assessment

Please see Chapter 2 Harmonised classification and labelling.

5. Environmental hazard assessment

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (c) of REACH.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Orthoboric acid, sodium salt is covered by index number 005-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and is classified in the hazard class toxic for reproduction category 1B (H360FD).

Therefore, the classification of the substances covered by this (generic) entry in Regulation (EC) No 1272/2008 shows that they meet the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Part II

7. Registration and C&L notification status

7.1 Registration status

The substances are not registered under REACH.

7.2 CLP notification status

Table 3: CLP notifications

	CLP Notifications ²
Number of aggregated notifications	6
Total number of notifiers	763

8. Total tonnage of the substances

The substances are not registered. No information.

Table 4: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)	No information/Not registered
Tonnage information from public sources other than registration dossiers (if available)	No information

9. Information on uses of the substances

Orthoboric acid, sodium salt is not registered under REACH and thus no information on uses is available. However, there is some, although very limited, information on the uses of orthoboric acid, sodium salt. The SPIN (Substances in Preparations In the Nordic countries) database³ indicates occupational and consumer uses of orthoboric acid, sodium salt. Uses include solvent and corrosion inhibitor.

The closely related sodium borates already included in the Candidate list have widespread uses which includes corrosion inhibitor (see 11.1 below for further details). Since orthoboric acid, sodium salt is expected to have similar properties as these sodium

² C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 21 September 2020)

³ <http://spin2000.net/> (accessed 21 September 2020)

borates, it may be used as an alternative. Hence, there is a potential risk for regrettable substitution.

10. Information on structure of the supply chain

No information identified.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

Several sodium borates are already included in the Candidate list (reason for inclusion: toxic for reproduction): disodium tetraborate, anhydrous (CAS no 1330-43-4; EC no 215-540-4), disodium tetraborate decahydrate (CAS no 1303-96-4; EC no 215-540-4; synonym: borax decahydrate), disodium tetraborate pentahydrate (CAS no 12179-04-3; EC no 215-540-4; synonym: borax pentahydrate), disodium octaborate (CAS no 12008-41-2; EC no 234-541-0), and tetraboron disodium heptaoxide, hydrate (CAS no 12267-73-1; EC no 235-541-3).⁴

Orthoboric acid, sodium salt is currently the only sodium borate with a harmonised classification for reproductive toxicity which has not already been proposed to be identified as an SVHC.

In aqueous solutions at physiological and acidic pH, low concentrations of sodium borates (including orthoboric acid, sodium salt) will predominantly exist as undissociated boric acid. The toxicokinetics and toxicological effects of these borates will therefore be expected to be similar on a boron equivalent basis. Hence, read-across from boric acid to other borates and between borates has long been accepted in a regulatory context. These similar properties should also be taken into account when considering the potential use of orthoboric acid, sodium salt as an alternative to other sodium borates.

Most of the sodium borates that are in the Candidate list have numerous and diverging uses. The sodium borates with the highest tonnage are substances with EC No 215-540-4; Disodium tetraborate (anhydrous, pentahydrate, decahydrate), also known as borax. Borax is used as *e.g.* corrosion inhibitor, buffering agent, lubricant, adhesive, and as a component in glass and ceramics. There is a very limited amount of information on the use of orthoboric acid, sodium salt. However, it is used as corrosion inhibitor. Further, since orthoboric acid, sodium salt is expected to have similar properties as the other sodium borates, it may be used as an alternative. Hence, there is a potential risk for regrettable substitution.

⁴ <https://echa.europa.eu/candidate-list-table> (accessed 21 September 2020)

11.2 Existing EU legislation, in addition to CLP

Orthoboric acid, sodium salt is covered by the following legislations:

- CAD - Chemical Agents Directive⁵
- Cosmetic Products Regulation⁶
- EU Ecolabel Regulation⁷
- Protection of Pregnant and Breastfeeding Workers Directive⁸
- Protection of Young People Directive⁹
- Safety and/or Health Signs at Work Directive¹⁰
- WFD - Waste Framework Directive¹¹

⁵ EU. Hazardous Substances - Art. 2(b)(i), Directive 98/24/EC on Protection of Workers from Chemical Agent-related Risks, 5 May 1998 (Table 3 of Annex VI to CLP, as amended)

⁶ EU. Prohibited Substances: Annex II, Regulation 1223/2009/EC on Cosmetic Products, as amended by Regulation 2019/1966/EU, 28 November 2019

⁷ EU. Substances Rendering Goods Ineligible for EU Ecolabel, Art. 6(6), Reg. 66/2010/EC, L 27/1, 30 Jan 2010 (T. 3 of Anx VI to CLP; Candidate List of SVHCs)

⁸ EU. Chemical Agents: Annexes I & II, Dir. 92/85/EEC on Pregnant Workers, 28 November 1992 (updated by table 3 of Annex VI to CLP, 5 Oct 2018)

⁹ EU. Non-Exhaustive List of Banned Substances, Directive 94/33/EC on Young People at Work, 20 August 1994, as amended by Dir 2014/27/EU, March 5, 2014 (Based on Table 3 of Annex VI to CLP, inter alia)

¹⁰ EU. Workplace Signage: Annexes I and III, Directive 92/58/EEC, last amended by Directive 2014/27/EU, 5 March 2014

¹¹ EU. Substances according to Hazardous Waste Properties: Annex III, Directive 2008/98/EC, 22 November 2008, amended by Directive 2018/851/EU, 14 June 2018

REFERENCES

References for Part I

EU (2006). 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 (REACH), establishing a European Chemicals Agency, 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. Official Journal of the European Union, L396: 1-849.

EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.

References for Part II

ECHA (2011): Annex XV dossier - identification of SVHC, Disodium tetraborate, anhydrous, Denmark, 2010. Published on ECHA's website: <https://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations>