

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: Barium diboron tetraoxide

EC Number: 237-222-4

CAS Number: 13701-59-2

Submitted by: Swedish Chemicals Agency

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PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance name: Barium diboron tetraoxide

EC number: 237-222-4

CAS number: 13701-59-2

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B¹.

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

Barium diboron tetraoxide is covered by index number 056-005-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (360FD²).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets 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: Yes

¹ Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

² H360FD: 'May damage fertility. May damage the unborn child'.

PART I

Justification

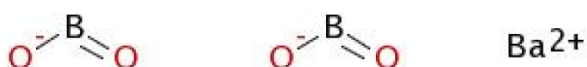
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	237-222-4
EC name:	Barium diboron tetraoxide
CAS number:	13701-59-2
IUPAC name:	Barium diboron tetraoxide
Index number in Annex VI of the CLP Regulation	056-005-00-3
Molecular formula:	BaB ₂ O ₄
Molecular weight:	222.95 g/mol
Synonyms:	Barium metaborate Boric acid (HBO ₂), barium salt (2:1) Boric acid (HBO ₂), barium salt Barium borate Barium boron oxide Barium(2+);oxido(oxo)borane Barium(2+) ion boronato

Structural formula:



Identifiers for hydrated forms of the substance are also within the scope of the entry: *e.g.*, boric acid (HBO₂), barium salt, monohydrate (CAS number 19004-06-9) and boric acid (HBO₂), barium salt, dihydrate (CAS number 38720-52-4).

1.2 Composition of the substance

Name: Barium diboron tetraoxide

Description: Inorganic

Substance type: mono-constituent

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

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

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

Barium diboron tetraoxide is covered by Index number 056-005-00-3 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 and ATEs ³	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)		
056-005-00-3	Barium diboron tetraoxide	237-222-4	13701-59-2	Repr. 1B Acute Tox. 4 Acute Tox. 3	H360FD H332 H301	GHS08 GHS06 Dgr	H360FD H332 H301		inhalation: ATE = 1,5 mg/L (dusts or mists) oral: ATE = 100 mg/kg bw	

³ Acute Toxicity Estimate

3. Environmental fate properties

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

4. Human health hazard assessment

The RAC opinion on the proposed harmonised classification and labelling of the substance barium diboron tetraoxide as Repr. 1B (H360FD), Acute Tox. 3 (H301) and Acute Tox. 4 (H332) was adopted on 17 September 2020 by consensus (RAC, 2020). The substance was added to Table 3, Annex VI of CLP via Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 (EU, 2022).

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Barium diboron tetraoxide is covered by index number 056-005-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360FD⁴).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

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

⁴ H360FD: 'May damage fertility. May damage the unborn child.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3: Registration status

From the ECHA dissemination site ⁵	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications ⁶
Number of aggregated notifications	7
Total number of notifiers	399

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁵	100-1,000 t/pa
Tonnage information from public sources other than registration dossiers (if available)	No information

⁵ Barium diboron tetraoxide entry on ECHA dissemination site: <https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/15812/1/2> (accessed 16 March 2022)

⁶ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 16 March 2022)

9. Information on uses of the substance

Table 6: Uses

	Uses	Registered use	Use likely to be in the scope of Authorisation
Uses as intermediate	-	-	-
Formulation or repacking	Repacking of powder Formulation in paint PC 9a: Coatings and paints, thinners, paint removes Coating of PVC truck foil and coating of electrical wire PC 32: Polymer preparations and compounds	Yes	Yes
Uses at industrial sites	Coating/painting of articles PC 9a: Coatings and paints, thinners, paint removes	Yes	Yes
Uses by professional workers	Use in paint PC 9a: Coatings and paints, thinners, paint removes	Yes	Yes
Consumer uses	Use in paint PC 9a: Coatings and paints, thinners, paint removes	Yes	No
Article service life	-	-	-

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 inorganic boron compounds, in which boron is bonded exclusively to oxygen and that are often referred to as borates, are already included in the Candidate List (reason for inclusion: toxic for reproduction). Examples of such substances include: 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), tetraboron disodium heptaoxide, hydrate (CAS no 12267-73-1; EC No 235-541-3), and orthoboric acid, sodium salt (CAS No 13840-56-7; EC No 237-560-2 and related identifiers mentioned in the Candidate List).⁷ Barium diboron tetraoxide is currently the only

⁷ <https://echa.europa.eu/candidate-list-table> (accessed 16 March 2022)

inorganic borate with a harmonised classification for reproductive toxicity which has not yet been proposed to be identified as an SVHC.

In aqueous solutions at physiological and acidic pH, low concentrations of this type of inorganic borates (including barium diboron tetraoxide) will predominantly exist as undissociated boric acid. The toxicokinetics and toxicological effects of these borates are therefore 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 barium diboron tetraoxide as an alternative to other sodium borates.

Barium diboron tetraoxide only has limited uses/functions (in formulation of paints and coatings). However, these uses/functions overlap with some of the uses/functions of borates currently included in the Candidate List according to their respective REACH registrations (e.g. disodium octaborate EC No 234-541-0 and borax EC No 215-540-4). Based on the identified overlaps of uses/functions and the chemical similarities, barium diboron tetraoxide may be used as an alternative to these borates. Hence, there is a potential risk for regrettable substitution.

11.2 Alternatives

Possible alternatives for barium diboron tetraoxide in formulation of paints and coatings have been identified based on overlapping uses and functions in the SPIN database⁸ and in their respective REACH registrations: calcium phosphate, calcium molybdate, aluminium hydroxide and magnesium hydroxide.

11.3 Existing EU legislation

In addition to the CLP Regulation (EU, 2008, 2022), barium diboron tetraoxide is covered by the following legislation:

- CAD - Chemical Agents Directive⁹
- Cosmetic Products Regulation¹⁰
- EU Ecolabel Regulation¹¹
- Protection of Pregnant and Breastfeeding Workers Directive¹²
- Protection of Young People Directive¹³
- Safety and/or Health Signs at Work Directive¹⁴
- WFD - Waste Framework Directive¹⁵
- Within the near future barium diboron tetraoxide is foreseen to be included in REACH Annex XVII entry 30 (CLH reproductive toxicant category 1B)¹⁶

⁸ The SPIN database. <http://spin2000.net/> (accessed 16 March 2022)

⁹ 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)

¹⁰ EU. Prohibited Substances: Annex II, Regulation 1223/2009/EC on Cosmetic Products

¹¹ EU. Substances Rendering Goods Ineligible for EU Ecolabel, Art. 6(6), Reg. 66/2010/EC, L 27/1, 30 Jan 2010 (T. 3 of Annex VI to CLP; Candidate List of SVHCs)

¹² 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)

¹³ 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)

¹⁴ EU. Workplace Signage: Annexes I and III, Directive 92/58/EEC, last amended by Directive 2014/27/EU, 5 March 2014

¹⁵ 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

¹⁶ 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

REFERENCES

References for Part I

Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of barium diboron tetraoxide. 17 September 2020. Available at <https://echa.europa.eu/documents/10162/19507471-2f49-9564-d788-0452b1e124ab>

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.

EU (2022). Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union, L129: 1-17.

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.