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: Disodium octaborate

EC Number: 234-541-0

CAS Number: 12008-41-2

Submitted by: Swedish Chemicals Agency

Date: 22 February 2018

CONTENTS

TABLES

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

Substance Name: Disodium octaborate

EC Number: 234-541-0

CAS Number: 12008-41-2

- 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 reproductive toxicity category 1B[1].

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

The classification of disodium octaborate is based on the classification of two substances i.e., disodium octaborate anhydrate and disodium octaborate tetrahydrate. These two substances are covered by index number 005-020-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class reproductive toxicity category 1B (H360FD[1]). The proposed classification and labelling of disodium octaborate anhydrate and disodium octaborate tetrahydrate for reproductive toxicity is based on read-across from other tested borates (e.g. boric acid) and borate salts (borax or disodium tetraborate decahydrate) because their hydrolysis results in the formation of the same substances. The resulting classification is comparable to that of the other borates in Annex VI of Regulation (EC) No 1272/2008.

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

- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

[1] H360FD: May damage fertility. May damage the unborn child.

PART I

Justification

1. Identity of the substance and physical and chemical properties

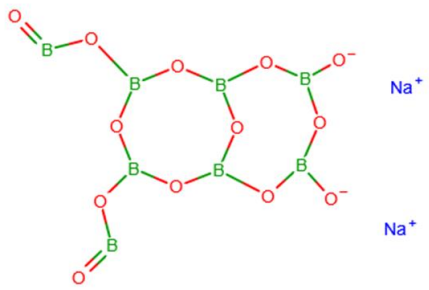
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	234-541-0
EC name:	Disodium octaborate
CAS number (in the EC inventory):	12008-41-2 (Disodium octaborate anhydrate)
CAS name:	Boron sodium oxide ($B_8Na_2O_{13}$)
IUPAC name:	disodium octaborate
Index number in Annex VI of the CLP Regulation	005-020-00-3
Molecular formula:	$B_8Na_2O_{13}$
Molecular weight range:	340.459 g/mol
Synonyms:	disodium octaborate Disodium Octaborate Tetrahydrate

It should be noted that EINECS numbers include both anhydrous and hydrated forms of a substance. There are frequently different CAS numbers for anhydrous and hydrated forms. The CAS number associated to the EINECS number is often for the anhydrous form only, and therefore the CAS number shown does not always describe the entry as accurately as the EINECS number. In this case, for example, EC entry 234-541-0 covers also the substance disodium octaborate tetrahydrate, CAS 12280-03-4.

Structural formula:



1.2 Composition of the substance

Name: Disodium octaborate

Description: Inorganic

Substance type: Mono-constituent

Degree of purity: Minimum concentration level: 80%

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) 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 substance as SVHC in accordance with Article 57 (c) REACH.

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

The classification of disodium octaborate is based on the classification of two substances i.e., disodium octaborate anhydrate and disodium octaborate tetrahydrate. The classification of the two substances is based on read-across from other tested borates (e.g. boric acid) and borate salts (borax or disodium tetraborate decahydrate). Hydrolysis of borates results in the formation of the same chemical entities (boron, B). The resulting classification is comparable to that of the other borates in Annex VI of CLP (RAC 2014a and 2014b).

These two substances (EC number 234-541-0) are covered by index number 005-020-00-3 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	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)		
005-020-00-3	disodium octaborate anhydrous	234-541-0	12008-41-2	Repr. 1B	H360FD	GHS08 Dgr	360FD	-	-	-
005-020-00-3	disodium octaborate tetrahydrate	234-541-0	12280-03-4							

3. Environmental fate properties

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

4. Human health hazard assessment

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

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

The classification of disodium octaborate is based on the classification of two substances i.e., disodium octaborate anhydrate and disodium octaborate tetrahydrate. These two substances are covered by the same EC number and index number 005-020-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances), and are classified in the hazard class reproductive toxicity category 1B (H360FD[2]).

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

- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

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

6.2 PBT and vPvB assessment

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

6.3 Assessment under Article 57(f)

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

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3 Registration status

From the ECHA dissemination site[3]	
Registrations	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications[4]
Number of aggregated notifications	7
Total number of notifiers	175

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]	1 000 - 10 000 t/pa

9. Information on uses of the substance

Disodium octaborate is manufactured and/or imported into the European Union in volumes between 1 000 - 10 000 tonnes per year. The substance is registered as a mono-constituent substance through a joint submission by five registrants. Some of the uses of disodium octaborate are listed in Table 6.

[3] *https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.031.388 (01-11-2017)*
[4] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 20-02-2018)
[5] *https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.031.388 (01-11-2017)*

Table 6: Uses

	Use(s)	Registered use	Use in the scope of Authorisation
Uses as intermediate	Manufacture of new chemicals.	Yes	No
Formulation or repacking	Disodium octaborate is used in: - formulation in micronutrient fertilisers and in refractory mixtures. - formulation of cellulose insulation, of paints and coatings, of construction materials, and of borate PVA solutions. - formulation into cement. - manufacture of flux mixtures and pastes.	Yes	Yes
Uses at industrial sites	Disodium octaborate is used at industrial sites: - in production of frits. - in use of paints and coatings, of cellulose insulation, and of cement.	Yes	Yes
Uses by professional workers	Disodium octaborate is used by professional workers in: - paints and coatings. - micronutrient fertilisers. - cellulose insulation. - construction materials.	Yes	Yes
Consumer uses	Consumer use of disodium octaborate include micronutrient fertilisers and construction materials.[6]	Yes	No
Article service life	Articles service life of disodium octaborate includes frits, cellulose insulation, and construction materials, flux mixtures and refractory mixtures (including stone, plaster, cement, glass and ceramic articles, and wood articles).	Yes	Yes

[6] The consumer use will, from 1 March 2018, no longer be allowed as disodium octaborate is included in entry 30 of Annex XVII to Regulation (EC) No 1907/2006 (REACH). Entry 30 prohibits the placing on the market or use for supply to the general public of substances that are classified as reproductive toxicant category 1A or 1B, and of mixtures containing such substances above specified concentrations.

In summary, disodium octaborate has *wide dispersive use* covering:

- widespread use - industrial use, professional use, consumer use[7] and articles service life.
- high potential of human exposure through, for example, PROC 10 (roller application or brushing), PROC 11 (non-industrial spraying), PROC 13 (treatment of articles by dipping and pouring), PROC 15 (use as laboratory reagent), PROC 19 (hand-mixing with intimate contact and only PPE available), PROC 23 (open processing and transfer operations with minerals/metals at elevated temperature) and PROC 24 (high (mechanical) energy work-up of substances bound in materials and/or articles).

10. Information on structure of the supply chain

Disodium octaborate is registered by five registrants affiliated in Italy, United Kingdom and Luxemburg. Moreover, 175 manufacturers/importers have notified the chemical in the classification and labelling inventory. The substance is used throughout the supply chain covering industry, professional workers and consumers (Table 6). Disodium octaborate is manufactured/imported in high tonnages and used in a number of different applications and for different products within the manufacturing industry, the construction industry, the ceramic and glassware industry, the farming industry, and for indoor and outdoor facilities.

11. Additional information

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

Table 7: Boron containing substances on the Candidate List (as of 8 August 2017)

Name	EC-number	CAS-number (EC-inventory)	Reason for inclusion
Boric acid	233-139-2	10043-35-3	Toxic for reproduction (Article 57c)
Boric acid, crude natural	234-343-4	11113-50-1	Toxic for reproduction (Article 57c)
Diboron trioxide	215-125-8	1303-86-2	Toxic for reproduction (Article 57c)
Disodium tetraborate, anhydrous	215-540-4	12179-04-3, 1303-96-4, 1330-43-4	Toxic for reproduction (Article 57c)
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	Toxic for reproduction (Article 57c)
Sodium perborate	239-172-9	15120-21-5	Toxic for reproduction (Article 57c)
Perboric acid, sodium salt	234-390-0	11138-47-9	Toxic for reproduction (Article 57c)
Sodium peroxometaborate	231-556-4	7632-04-4	Toxic for reproduction (Article 57c)
Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	Toxic for reproduction (Article 57c)

[7] The risk of exposure among consumers will decrease from 1 March 2018 as disodium octaborate will no longer be allowed to be placed on the market or used for supply to the general public (entry 30 of Annex XVII to Regulation (EC) No 1907/2006).

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

The classification and labelling of disodium octaborate for reproductive toxicity is based on read-across from other tested borates (e.g. boric acid) and borate salts (borax or disodium tetraborate decahydrate) because the hydrolysis results in the formation of the same substances.

11.2 Alternatives

In a recently published report by the Danish Environmental Protection Agency (DEPA, 2015), it was concluded that there does not seem to be suitable alternatives for the majority of the uses of the borates on the Candidate list for the glass industry, for starch and dextrin adhesives, for fertiliser or for lubricating oil. However, the Danish Agency found that there seem to be alternatives available in other sectors, such as surface coatings and paints, insulation materials, welding processes, pH buffer solutions and in diagnostic applications.

11.3 Existing EU legislation, in addition to CLP

Commission Regulation (EU) 2017/1510, amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006, prohibits the placing on the market or use for supply to the general public of disodium octaborate anhydrous and disodium octaborate tetrahydrate based on their classification as reproductive toxicants category 1B. From 1 March 2018, disodium octaborate will no longer be allowed (entry 30).

Commission Directive 2009/96/EC, amending Directive 98/8/EC of the European Parliament and of the Council, lists disodium octaborate tetrahydrate as an active substance in biocidal products in Annex I (EU 2009). Biocidal products used as wood preservatives and containing disodium octaborate tetrahydrate can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

In Regulation (EC) 1223/2009, disodium octaborate anhydrous and disodium octaborate tetrahydrate are covered by the substances boric acid, borates and tetraborates in Annex III entry 1a, list of substances that cosmetic products must not contain except subject to the restrictions laid down in the regulation (SCCS, 2010).

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.

RAC (2014a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of Disodium Octaborate Anhydrate, EC number: 234-541-0, CAS number: 12008-41-2, CLH-O-0000003654-72-03/F, Adopted 14 March 2014, European Chemicals Agency (ECHA).

RAC (2014b). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of Disodium Octaborate Anhydrate, EC number: 234-541-0, CAS number: 12008-41-2, CLH-O-0000003654-72-03/F, Adopted 14 March 2014, European Chemicals Agency (ECHA).

References for Part II

DEPA (2015). Danish Environmental Protection Agency (DEPA), Survey of Boric acid and sodium borates (borax), Survey of chemical substances in consumer products No. 139, 2015.

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 (2009). Assessment report. Disodium octaborate tetrahydrate, Product-type 8 (wood-preservative), 20 February 2009. Directive 98/8/EC concerning the placing biocidal products on the market Inclusion of active substances in Annex I or IA to Directive 98/8/EC.

EU (2009). Commission Directive (EC) No 2009/96 of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate as an active substance in Annex I thereto. Official Journal of the European Union, L 201/58.

EU (2009). Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Official Journal of the European Union L 342/59.

EU (2017). Regulation (EU) No 2017/1510 amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR substances. Official Journal of the European Union, L 224/110.

SCCS (2010). Scientific Committee on Consumer Safety (SCCS). Opinion on Boron compounds. SCCS/1249/09, Revision of 28 September 2010. The SCCS adopted this opinion at its 7th plenary meeting of 22 June 2010.