

Substance Name: Disodium octaborate

EC Number: 234-541-0

CAS Number: 12008-41-2

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF
DISODIUM OCTABORATE

AS A SUBSTANCE OF VERY HIGH CONCERN
BECAUSE OF ITS TOXIC FOR REPRODUCTION
PROPERTIES

(ARTICLE 57C)

Adopted on 1 June 2018

CONTENTS

IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57	4
JUSTIFICATION	5
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	5
1.1 Name and other identifiers of the substance	5
1.2 Composition of the substance	6
1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment	6
1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)	6
1.5 Physicochemical properties	6
2. HARMONISED CLASSIFICATION AND LABELLING	6
3. ENVIRONMENTAL FATE PROPERTIES	7
4. HUMAN HEALTH HAZARD ASSESSMENT	7
5. ENVIRONMENTAL HAZARD ASSESSMENT	7
6. CONCLUSIONS ON THE SVHC PROPERTIES	7
6.1 CMR assessment	7
6.2 PBT and vPvB assessment	8
6.3 Assessment under Article 57(f)	8
REFERENCES	9

TABLES

Table 1: Substance identity	5
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	7

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 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 1B¹.

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 (H360FD¹). The 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.

Justification

1. Identity of the substance and physical and chemical properties

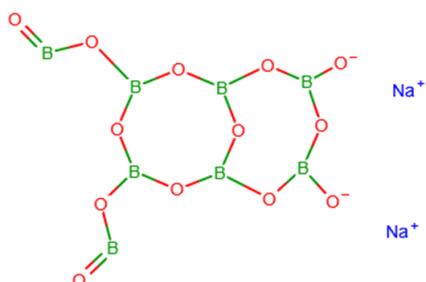
1.1 Name and other identifiers of the substance

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. A substance included in the candidate list is normally described by the identifiers as published in the EC inventory. In this case CAS entry 12008-41-2 is associated to EC entry 234-541-0 therefore it is envisaged to specify this CAS entry in the Candidate List. However indicating the CAS number of the specific hydrated form in the Candidate List entry may create ambiguities on whether hydrated forms other than the tetrahydrate would be covered by the entry. For this reason, it is not planned to list the CAS number for the hydrated form (CAS 12280-03-4) in the Candidate List.

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

1.5 Physicochemical properties

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

4. Human health hazard assessment

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

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of 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 (H360FD²).

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) of REACH.

6.3 Assessment under Article 57(f)

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

References

- 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).