

AGREEMENT OF THE MEMBER STATE COMMITTEE  
ON THE IDENTIFICATION OF  
DISODIUM OCTABORATE  
AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of  
Regulation (EC) 1907/2006<sup>1</sup>

Adopted on 1 June 2018

This agreement concerns

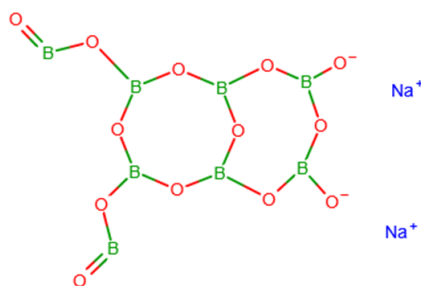
Substance name: Disodium octaborate

EC number: 234-541-0

CAS number: 12008-41-2

Molecular formula:  $B_8Na_2O_{13}$

Structural formula:



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<sup>1</sup>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

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (01 March 2018, submission number SPS-014058-18) on identification of *Disodium octaborate* as a substance of very high concern due to its toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 8 March 2018|and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 22 May 2018 and agreed in the written procedure of the Member State Committee with closing date of 1 June 2018.

Agreement of the Member State Committee in accordance with Article 59(8):

*Disodium octaborate* is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) as this substance meets the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008<sup>2</sup>.

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<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

UNDERLYING ARGUMENTATION  
FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

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). 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 it meets the criteria for classification in the hazard class:

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

Reference:

Support Document on *disodium octaborate* (Member State Committee, 1 June 2018)