



AGREEMENT OF THE MEMBER STATE COMMITTEE

**ON THE IDENTIFICATION OF TETRABORON DISODIUM HEPTAOXIDE,
HYDRATE**

AS A SUBSTANCE OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006 (REACH)¹**

Adopted on 9 June 2010

This agreement concerns

Substance name: Tetraboron disodium heptaoxide, hydrate

EC number: 235-541-3

CAS number: 12267-73-1

Molecular formula: Na₂B₄O₇•xH₂O

¹ 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

Denmark presented a proposal in accordance with Article 59(3) and Annex XV of REACH (5 March 2010, submission number CE010448-60) on the identification of *tetraboron disodium heptaoxide, hydrate* as a substance of very high concern because of its toxic for reproduction properties.

Pursuant to Articles 59(3) and 59(4) of REACH the Annex XV dossier was circulated to Member States on 8 March 2010 and the Annex XV report was made available to interested parties on the ECHA website on the same day.

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

The dossier was referred to the Member State Committee on 25 May 2010 and was discussed in the meeting of the Committee on 9-10 June 2010.

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

***Tetraboron disodium heptaoxide, hydrate* is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction (category 2)².**

² Category in accordance with Annex I to Council Directive 67/548/EEC

**UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN**

Toxicity for reproduction:

Pursuant to Annex V of Commission Regulation (EC) No 790/2009³ as of 1 December 2010 *tetraboron disodium heptaoxide, hydrate* will be listed in Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Annex VI, part 3, of Regulation (EC) No 1272/2008⁴ as toxic for reproduction category 2⁵, R60-61 (May impair fertility. May cause harm to the unborn child).

Therefore, this classification of the substance in Commission Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Reference:

1. Support Document *Tetraboron disodium heptaoxide, hydrate* (Member State Committee, 9 June 2010)

³ Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (1st ATP)

⁴ 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.

⁵ This corresponds to a classification Repr. 1B; H360-FD (May damage fertility. May damage the unborn child) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances).