

**1 September 2014**

## **Draft background document for Tetraboron disodium heptaoxide, hydrate**

### **Document developed in the context of ECHA's sixth Recommendation for the inclusion of substances in Annex XIV**

*ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.*

## **1. Identity of the substance**

Chemical name: tetraboron disodium heptaoxide, hydrate

EC Number: 235-541-3

CAS Number: 12267-73-1

IUPAC Name: tetraboron disodium heptaoxide, hydrate

## **2. Background information for prioritisation**

*Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation<sup>1</sup>. Results of the prioritisation of all substances included in the Candidate List by June 2013 and not yet included or recommended in Annex XIV of the REACH Regulation is available at*

[http://echa.europa.eu/documents/10162/13640/prioritisation\\_results\\_6th\\_rec\\_en.pdf](http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf).

### **2.1. Intrinsic properties**

Tetraboron disodium heptaoxide, hydrate was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

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<sup>1</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

## 2.2. Volume used in the scope of authorisation

There are no registrations for tetraboron disodium heptaoxide, hydrate under Regulation (EC) No 1907/2006 (REACH).<sup>2</sup>

## 2.3. Wide-dispersiveness of uses

There are no registrations for tetraboron disodium heptaoxide, hydrate under Regulation (EC) No 1907/2006 (REACH).

## 2.4. Further considerations for priority setting

Tetraboron disodium heptaoxide, hydrate has structural similarities with boric acid, disodium tetraborate anhydrous, and diboron trioxide. The latter substances were prioritised for inclusion in Annex XIV. The substances have the potential to be used in the same types of application. Grouping was therefore considered for priority setting.

## 2.5. Conclusions and justification

On the basis of grouping considerations, tetraboron disodium heptaoxide, hydrate is proposed to be recommended for inclusion in Annex XIV.

## 3. Further information on uses

According to information submitted, by an industry association, during the public consultation on SVHC identification (RCOM, 2010), tetraboron disodium heptaoxide hydrate is used in nuclear power plants, and more specifically in boiling water reactors together with boric acid. The function of tetraboron disodium heptaoxide is as a preservative agent for the respective closed cooling systems. Final concentration in the cooling systems is reported as 0.2% (w/w).

## 4. Background information for the proposed Annex XIV entry

*Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV<sup>3</sup>. The draft Annex XIV entries for substances included in this draft recommendation are available at [http://echa.europa.eu/documents/10162/13640/draft\\_axiv\\_entries\\_summarytable\\_6th\\_en.pdf](http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_summarytable_6th_en.pdf). The section below provides background for allocation of the substance to the Latest Application Date slots.*

The LAD slots are set in 3 months intervals (i.e. 18, 21 and 24 months after inclusion in Annex XIV).

Borates have been considered to be placed in the same slot as they may fulfil the definition of a group according to section 1.5 of Annex XI of REACH (provision allowing submitting common applications for authorisation).

The allocation of (group of) substances to LAD slots aims at an even workload for all parties

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<sup>2</sup> Number of registrations as of 21 May 2014

<sup>3</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/draft\\_axiv\\_entries\\_gen\\_approach\\_6th\\_en.pdf](http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf)

during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD, however the time differences between the LADs set out in a recommendation (i.e. 3-6 months) can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications.

Substances for which the preparation of the application may require longer time are assigned to the later LAD slots (2<sup>nd</sup> and 3<sup>d</sup>). Borates (including tetraboron disodium heptaoxide, hydrate) are assigned to the latest LAD slots due to the apparently high number of uses and overall complexity of supply chain.

## 5. References

Annex XV report (2010): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Tetraboron disodium heptaoxide, hydrate. Submitted by Denmark, February 2010.

[http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern-previous-consultations?search\\_criteria=235-541-3](http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern-previous-consultations?search_criteria=235-541-3)

RCOM (2010): "*Responses to comments*" document. Document compiled by Denmark from the commenting period 08/03/2010-22/04/2010 on the proposal to identify Tetraboron disodium heptaoxide, hydrate as a Substance of Very High Concern.

<http://echa.europa.eu/documents/10162/d5da8a7f-995e-4f51-b121-f260f72b15a2>