

1 July 2015

Background document for tetraboron disodium heptaoxide, hydrate

Document developed in the context of ECHA's 6th 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 authorisation¹. 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.

The prioritisation results of the substances included in the draft 6th recommendation have been updated as necessary after the public consultation. The updated results are available at

http://echa.europa.eu/documents/10162/13640/updated_prioritisation_results_6th_axiv_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, H360FD (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.

¹ Document can be accessed at

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).²

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. All four 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 recommended for inclusion in Annex XIV.

3. Further information on uses

According to information submitted by industry, during the public consultations on SVHC identification and draft Annex XIV recommendation (RCOM 2010 and ComRef 2015), 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, hydrate is as a preservative agent for the respective closed cooling systems. Final concentration in the cooling systems is reported as 0.2% (w/w). One association informed during the public consultation on the draft Annex XIV recommendation (ComRef, 2015) that the substance is used in cleaning solutions and alkaline degreasing baths.

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 XIV³. The draft Annex XIV entries for substances included in the 6th recommendation are available at http://echa.europa.eu/documents/10162/13640/6th_axiv_recommendation_july2015_en.pdf. The section below provides background for allocation of the substance to the Latest Application Dates slots.

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis).

² As of 1 December 2014

³ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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 during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively high number of uses. Substances with no registration requirement are also allocated to the later slots.

Borates (including tetraboron disodium heptaoxide, hydrate) are assigned to the latest LAD slot (27 months after inclusion in Annex XIV) 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

ComRef (2015): "Comments and references to responses" document for tetraboron disodium heptaoxide, hydrate". Document compiling comments and references to respective answers from commenting period 01/09/2014 -01/12/2014 on ECHA's 6th draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_tetraboron_disodium_heptaoxide_hydrate_en.pdf

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>