

1 September 2014

Draft background document for Disodium tetraborate, anhydrous

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: Disodium tetraborate, anhydrous; boric acid, disodium salt

EC Number: 215-540-4

CAS Number: 1330-43-4, 12179-04-3, 1303-96-4

IUPAC Name: Disodium tetraborate anhydrous

The description covers also disodium tetraborate hydrates covered by the EINECS entry of anhydrous form.

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.

2.1. Intrinsic properties

Disodium tetraborate, anhydrous 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.

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

The amount of disodium tetraborates manufactured and/or imported into the EU is according to registration data (the latter including also figures collected by European Borates Association (EBA) regarding the year 2012 and submitted by the Lead Registrant - on behalf of the co-registrants - in an update of his registration dossier) in the range of 100,000 – 1.000,000 t/y. Some uses appear not to be in the scope of authorisation, such as uses as intermediate in the manufacture of other substances (including in the glass and ceramic/frit sectors) and uses of mixtures below the specific concentration limit for classification (SCL), uses in cosmetic / medicinal / biocidal products, and laboratory uses. Taking into account the above referred to information by EBA, which reflects also allocation of volume per use, the volume in the scope of authorisation is estimated to be > 10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of disodium tetraborates in the scope of authorisation include:

- uses at industrial sites, including, formulations, uses of some mixtures, incorporation into articles, and use as processing aid. Such uses take place in a high number of sectors, main fields of application include, e.g., cellulose insulation, metallurgy, adhesives, construction materials, detergents, refractories, industrial fluids, paints and coatings, abrasives, swimming pool tablets, metal treatment, nuclear system, cement, and
- uses by professional workers, including formulation/use of fertilisers, use in cellulose insulation, construction materials, coatings, swimming pool tablets, detergents/cleaners, and potentially further registered uses.

In the above examples, where the substance is used as mixture, part of the mixtures supplied to the end use may contain the substance in concentrations below the SCL. For the professional uses listed there is information (in the EBA data reported in registration, in CSRs, or information from public consultation) that the respective mixtures are not limited to concentrations below the SCL. The same applies also for many of the industrial uses listed: most of them don't imply only formulation, but also end uses in the scope of authorisation (including mixtures \geq SCL).

Furthermore, article service life is relevant for several of the uses listed above, e.g. cellulose insulation, refractories, construction materials, coatings, metallic equipment, etc.

2.4. Conclusions and justification

Verbal descriptions and Scores			Total Score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
The substance is classified as toxic for reproduction 1B meeting the criteria 57c. Score: 1	The amount of disodium tetraborates used in the scope of authorisation is estimated to be > 10,000 t/y Score: 15	Disodium tetraborates are used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles. Refined score: 12	28

Conclusion

On the basis of the prioritisation criteria, disodium tetraborate, anhydrous received high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, it is proposed to recommend disodium tetraborate, anhydrous for inclusion in Annex XIV.

3. Further information on uses

Disodium tetraborate, anhydrous can exhibit a multitude of functions, depending on its use, such as micronutrient, flame retardant, complexing agent, stabiliser, corrosion inhibitor, flux agent, lubricant, buffering agent / pH-regulator, viscosity adjustor, oxidising agent, etc. Some of the main sectors of use in terms of tonnage (information from registrations and RCOM 2010) are described below.

Disodium tetraborate is a source of boron, which is an essential micronutrient required for crop nutrition. Boron is applied as straight fertilisers or added in a small quantity to NPK (nitrogen-phosphorus-potassium) fertilizers or in liquid specialties for foliar or soil application (RCOM, 2010).

Disodium tetraborate is used in cellulose insulation and construction materials (plaster board, wood-based board) as flame retardant.

There are many applications involving disodium tetraborate in metallurgy, industrial fluids, and abrasives, which concern numerous industrial sectors. Examples include metal surface treatment applications (e.g. plating, passivation, galvanising), metal surface cleaning / tumbling / polishing / degreasing, use in flux mixtures and pastes for precious metals smelting or for coating brazing and welding rods, lubricant oils, coolants, hydraulic fluids etc.

A further use is as binder in refractory mixtures. Disodium tetraborate is intended to increase the lifetime of refractory products. Such products are used e.g. in furnace lining and concern for instance the steel, glass, cement, and aluminium industry.

Information about further uses or specific applications is available in registrations and in RCOM (2010).

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 XIV². 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. The section below provides background for allocation of the substance to the Latest Application Date slots.

² Document can be accessed at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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 during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD but 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 (2nd and 3d). Borates (including disodium tetraborate, anhydrous) 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. Disodium tetraborate, anhydrous. Submitted by Denmark, February 2010.
<http://echa.europa.eu/documents/10162/a43277c9-70d1-4914-a429-8dc42b9ddd09>

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 Disodium tetraborate, anhydrous as a Substance of Very High Concern.
<http://echa.europa.eu/documents/10162/4967b1c1-f26f-4aef-9bcd-63b3f133d127>