

1 July 2015

Background document for disodium tetraborate, anhydrous

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: Disodium tetraborate, anhydrous
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 .

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

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

¹ Document can be accessed at

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

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.

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 in the range of 100,000 – 1,000,000 t/y. This assessment is based on registration data submitted by the Lead Registrant - on behalf of the co-registrants - in the latest update of the registration data in 2014. These include also figures collected by European Borates Association (EBA) that reflect the market situation of 2012 which represent the most up-to-date information available. Previous information on volume of uses of the substance (e.g. as cited in the Annex XV report proposing identification of disodium tetraborate, anhydrous as substance of very high concern) was not taken into account for priority assessment as it does not reflect the most recent market situation.

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 glass² and ceramic/frit sectors) and uses of mixtures below the specific concentration limit (SCL) for classification, 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 do not refer only to 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 Glass in this context also includes special glass and crystal.

2.4. Conclusions and justification

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

Conclusion

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

3. Further information on uses

Disodium tetraborate, can exhibit a multitude of functions, depending on its use, such as micronutrient, neutron absorption, 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, RCOM 2010 and ComRef 2015) are described briefly below.

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

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

Disodium tetraborate, anhydrous is furthermore used in the nuclear industry for its unique neutron absorbing capability to ensure nuclear safety.

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) and ComRef (2015).

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).

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 disodium tetraborate, anhydrous) 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.

³ Document can be accessed at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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>
- ComRef (2015): "Comments and references to responses" document for disodium tetraborate, anhydrous. 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_disodium_tetraborate_anhydrous_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 Disodium tetraborate, anhydrous as a Substance of Very High Concern. <http://echa.europa.eu/documents/10162/4967b1c1-f26f-4aef-9bcd-63b3f133d127>