

1 July 2015

Background document for diboron trioxide

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: diboron trioxide
EC Number: 215-125-8
CAS Number: 1303-86-2
IUPAC Name: diboron trioxide

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

Diboron trioxide 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 2012, following ECHA's decision ED/87/2012.

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 diboron trioxide manufactured and/or imported into the EU is according to registration data in the range of 1,000-10,000 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 boric acid 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 sectors, manufacture of other borates) and uses of mixtures below the specific concentration limit (SCL) for classification, uses in cosmetic / medicinal / biocidal products, and uses in SRD. 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 in the range of 100 – 1,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of diboron trioxide in the scope of authorisation include:

- uses at industrial sites, including formulation, 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., refractories, metallurgy, semiconductors and coatings; further registered uses include nuclear systems, soldering mixtures, flux agents for alloys and/or ceramic glazings, adhesive powders, abrasives, industrial fluids, construction materials, detergent cleaners, machinery and transport equipment, and
- uses by professional workers (seem to include uses in metallurgy, uses of coatings, soldering mixtures, flux agents for alloys and/or ceramic glazings, adhesive powders, fertilisers. There are further registered uses such as in abrasives, fluids, construction materials, and detergent cleaners. According to information from the SPIN database reported during the public consultation, diboron trioxide is potentially also used in other applications, e.g. in photo-chemicals, however for all these further uses no information regarding the concentration of diboron trioxide in the mixtures was available).

In the above examples, where the substance is used in mixtures, part of the mixtures supplied to the end use therefore may contain the substance in concentrations below the SCL.

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

It is noted that only a few from the registered uses have been reported by EBA as occurring in the EU in 2012.

² Glass in this context also includes special glass and crystal.

2.4. Further considerations

It appears that diboron trioxide could potentially replace boric acid and disodium tetraborate, anhydrous in some of their uses, as these substances have structural similarities and almost identical pattern of registered uses.

2.5. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
The substance is classified as toxic for reproduction 1B meeting the criteria 57c. Score: 1	The amount of diboron trioxide used in the scope of authorisation is estimated to be in the range of 100-1,000 t/y Score: 9	Diboron trioxide is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles. Refined score: 12	22	Diboron trioxide could potentially replace boric acid and disodium tetraborate, anhydrous in some of their uses.

Conclusion

On the basis of the prioritisation criteria and grouping considerations, diboron trioxide receives high priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, diboron trioxide is recommended for inclusion in Annex XIV.

3. Further information on uses

Based on registration information the substance can be used in many applications, exhibiting a multitude of functions, depending on its use, such as flame retardant, flux agent, oxidising agent, micronutrient, etc.

Based on information provided by EBA (RCOM 2012 and ComRef 2015), uses such as in refractories and in metallurgy appear to be among the main uses, in terms of tonnage, in the scope of authorisation.

Diboron trioxide is used as binder in refractory mixtures, with the aim 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 (RCOM, 2012) 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 diboron trioxide) 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 (2012): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Diboron trioxide. Submitted by Germany, February 2012.

<http://echa.europa.eu/documents/10162/9cb8329d-8a08-443d-8b33-2b04f6a54bae>

ComRef (2015): "Comments and references to responses" document for diboron trioxide. 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_diboron_trioxide_en.pdf

RCOM (2012): "Responses to comments" document. Document compiled by Germany from the commenting period 27/02/2012-12/04/2012 on the proposal to identify Diboron trioxide as a Substance of Very High Concern.

<http://echa.europa.eu/documents/10162/cf0334f4-e407-4dc7-afaf-96cfeab0c5e5>

³ Document can be accessed at

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