European Borates Association A.I.S.B.L.
Member of IMA-Europe

To: Borates Downstream Users (Trade Federations & Companies)

March 25th, 2013

Dear Sir, Madam,

In anticipation of the ECHA 2013 activities that could impact borates, the European Borates Associations (EBA) would like to provide you here below with an overview of the situation of borates – boric acid, disodium tetraborates and diboron trioxide – under REACH & CLP Regulations.

CLP activities

In December 2012, Poland submitted a CLH[1] re-classification dossier for boric acid to ECHA. Based on new scientific knowledge, the Polish dossier recommends re-classifying boric acid as Repr. 2 H361d (suspected of damaging the unborn child). Should European Chemicals Agency (ECHA), Risk Assessment Committee (RAC) and the European Commission agree with the Polish recommendation, boric acid would no longer meet the criteria for a Substance of Very High Concern (SVHC) and the restrictions for consumers[2] could be waived. A 45-day public consultation will be launched after the ECHA Accordance Check.

Poland has also notified its intention to submit a CLH dossier for diboron trioxide (by Dec 2013) and for disodium tetraborate (anhydrous, pentahydrate, decahydrate) (by Dec 2014). The classification and REACH registration dossiers of these substances are based on read-across to boric acid where information on the boron substance itself does not exist.

REACH activities

Registration dossiers updated:

The registrations dossiers for boric acid, disodium tetraborate and diboron trioxide have been updated in June 2012. The following changes have been made:

- Inclusion of a comparison of blood, semen and target organ boron levels in studies of laboratory animals and human studies
- Inclusion of new data for environmental endpoints (environmental fate, aquatic, sediment, marine and terrestrial ecotoxicity, and wastewater treatment)
- Exposure scenarios have been reviewed and the PNEC values have been changed for aquatic, sediment, marine, terrestrial and STP compartments.
- The presentation of the identified uses has been simplified
- Uses advised against have been updated to reflect Restrictions under Annex XVII (Regulation (EU) 109/2012) which since 1 June 2012 restricts the use of boric acid, disodium tetraborates and diboron trioxide above their respective specific concentration limit to professional and industrial uses.

[1] CLH : Classification & Labelling Harmonisation
[2] Regulation (EU) 109/2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances)

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Status of borates identified as SVHC

Currently, there are 138 Substances of Very High Concern (SVHC) on the candidate list amongst which 38 are already recommended for Authorisation. Boric acid and disodium tetraborates were identified as SVHCs in 2010 and diboron trioxide in 2012. None of these boron substances has yet been recommended for Authorisation. In 2011 and 2012, after careful consideration, ECHA (supported by the Member States) did NOT recommend boric acid and disodium tetraborate be prioritised for Authorisation.

As part of its annual activities, ECHA is now preparing its 5th recommendation of SVHCs to be prioritised for Authorisation. Member States Committee (MSC) discussions on ECHAs prioritisation results are scheduled for 22-26 April and 10-14 June 2013 with the objective to launch the 3-month public consultation by the end of June 2013. EBA is actively involved in the debate and argues that prioritization of boric acid, disodium tetraborates and diboron trioxide for Authorization would be inappropriate: it would be of no benefit to the health and safety of humans and a significant proportion of the uses are outside the scope of authorization due to use as either intermediate or covered by other legislation (e.g. biocide) or below the specific concentration limit. Decisions on any regulatory route should be based on proportionality and regulatory effectiveness. The main arguments supporting this EBA position are available upon request to the EBA Secretariat. Amongst these arguments, EBA advocates that no decision on prioritisation should be taken until the CLH dossier submitted by Poland on the re-classification of boric acid is assessed and a decision taken on it.

Should the regulatory status of these borates change, or where we believe that support from our Downstream Users would be beneficial we will inform or contact you again. In the meantime, the EBA and its members work closely with the relevant authorities.

On behalf of EBA, I would like to express our thanks to your organisation and its members for your continued support.

Sincerely,



Roger Doome
Secretary General