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

EBA comments on the consultation of Danish survey report on boric acid and sodium borates (part of the LOUS review)

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Although neither the European Borates Association (EBA) nor its members have been contacted during the developments of this report, we would like to take the opportunity of the public consultation to submit our comments on the survey of boric acid and sodium borates. The EBA represents the companies that manufacture or import 95% of the boric acid, 100% of the disodium tetraborates and 94% of the diboron trioxide in the EU.

COMMENTS ON THE USE OF CERTAIN REFERENCES

- *ECHA/transitional annex XV reports (2009a & b) for boric acid and disodium tetraborate anhydrous and the HERA report (2005)*
  The transitional dossiers do not provide the latest information submitted by industry. The transitional dossiers have been updated as a result of registration under REACH in 2010 and have been spontaneously updated in 2012 and 2014 in respect of new hazard data for both human health and the environment that were not available in 2009. These additional data include epidemiological data from Chinese and Turkish workers and data demonstrating that it is improbable that boric acid will cause reproductive or developmental effects in humans.

- *RPA (2008)*
  The RPA report (2008) does not portray a correct overview of the market size and uses of borates today.
  - The volume summary given in the RPA 2008 report includes sodium perborate which is not a substance included in this current review by LOUS. This leads to a misrepresentation of the volumes of boric acid, sodium tetraborates and boric oxide that are supplied specifically into the detergents market. EBA 2012 data indicates that only 1.5% is supplied for enzyme stabilisation in detergents. Even that volume of sodium tetraborate which is sold as a precursor for sodium perborate manufacture has sharply declined since 2008. Further, the majority of the sodium perborate manufactured in Europe is for export.
  - Although it is not possible for EBA Secretariat to comment on the specific imports and uses in Denmark, we can comment that the overall borate volumes in the EU market have shown a significant and continuing decline since 2008, stabilising since 2012 at around 300,000 metric tonnes.
  - EBA submitted volume information by sector during the recent public consultation by ECHA on whether to recommend boric acid, sodium tetraborates and boric oxide to the Commission for potential inclusion in Annex XIV of REACH. The EBA is willing to make these available to LOUS authors on a confidential basis.

- The REACH registration dossiers should be used to identify the current uses and exposures to these borates as this represents the current situation given that REACH registration has been required for these substances since 2010 and that those dossiers have been updated twice since.

CONTEXTUAL BACKGROUND FOR SOME USES REFERENCED WITHIN THE DRAFT LOUS REPORT

- Glass and ceramics

Glass and ceramics are manufactured through a series of complex chemical reactions resulting in a new substance that is chemically and physically different from the starting raw materials. A recent publication[1] describes the structural features of boron in glass and frits and the uses of such glasses. The article demonstrates that boron forms an integral part of the structure. This latter point in particular should be stated more clearly in the LOUS report.

Alternatives (Section 7): The patents that had previously restricted the implementation of continuous fibre glass with low or zero boron contents have now expired, however, the high temperatures and infrastructure required prevents the adoption of this technology in Europe.

- Coal fly ash

The boron levels in coal fly ash results from the natural levels present in coal deposits. Boron is a proven microessential nutrient for plant growth and is available to plants through the natural weathering of rocks. Therefore, the assertion that the high levels of boron in coal fly ash is due to man's activities is false.

- Cellulose insulation

Borates are added to recycled paper to provide flame retardancy. Ammonium salts had been identified as an alternative for borates, but proved to have their own safety issues in use due to the release of ammonia gas. As a consequence France submitted a proposal to restrict inorganic ammonium salts in cellulose insulation in 2014.

UPDATED INFORMATION ON VOLUMES OF BORATES IN THE EU

It is observed that overall borates volumes in the EU market have shown a significant and continuing decline since 2008. The figures for each substance are given below based on the latest data collected (2012).

Boric acid

The total volume placed on the market of boric acid in 2012 by EBA member companies was 91,212 metric tonnes, which represented 95% of the volume placed on the market in Europe. The remaining 5% was placed on the market by companies that are not members of EBA.

[1] Hubert, M. and Jans Faber, A., On the structural role of boron in borosilicate glasses, *Physics and Chemistry of Glasses: European Journal of Glass Science and Technology Part B* (volume 55, Number 3, pp 136-158).

Disodium tetraborates
The total volume placed on the market of disodium tetraborates in 2012 by EBA member companies was 203,362 metric tonnes, which represented 100% of the volume placed on the market in Europe.

Diboron trioxide
The total volume placed on the market of diboron trioxide in 2012 by EBA member companies was 1,227 metric tonnes, which represented 94% of the volume placed on the market in Europe.

As commented above, EBA believes that the REACH registration dossiers should be used as the basis for the today's uses in Europe.

SPECIFIC COMMENTS ON THE HUMAN HEALTH HAZARD ASSESSMENT AND EXPOSURE (SECTION 6)

6.1.2 **Acute toxicity**

In general, the boron compounds are of low acute toxicity after oral, dermal and inhalational administration in experimental animals.

In humans, acute poisoning can occur after oral and inhalation exposure as well as after dermal exposure via damaged skin. A human oral lethal dose is quoted to be 2-3 g boric acid for infants, 5-6g boric acid for children, and 15-30 g boric acid for adults (ECHA/RAC opinion (2010b). This may be the reason that some of the sodium borates have been classified as Acute Tox4; H302 in the company notifications to ECHA.

Comment

In the literature, the human oral lethal dose is regularly quoted as 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults based on an old case review by Goldbloom and Goldbloom (1953). However, this data is largely unsubstantiated and considerable confusion surrounds differences between acute and chronic boric acid ingestions. In most cases it is difficult to make a good quantitative judgment particularly since medical intervention occurred in most cases and there were often other unrelated medical conditions (Culver and Hubbard, 1996).

A review of previously reported cases indicates that much higher blood levels are well tolerated (Litovitz et al. 1988). Of more recent reports of accidental ingestion, none were reported as fatal and 88.3 % were asymptomatic. The estimated dose range was 10 mg to 88.8 g (Litovitz et al, 1988). Litovitz et al. (1988) conducted a meticulous review of prior reports of boric acid poisoning and found that prior reports of toxic effects following single acute ingestions of boric acid are few in number. Only two cases from the 1920s are the only fatalities following the acute ingestion of boric acid or sodium borate reported in the medical literature. The first case is a 66 year-old man following the accidental ingestion of 1 to 1.5 oz of borax (sodium borate) powder mistaken for a saline cathartic and a second case in 1928 of a fatality in a 53-year-old woman following the ingestion of four pancakes made from flour containing 51 % sodium borate. The authors found that the majority of acute boric acid ingestions produce no toxicity and that boric acid ingestions produce minimal toxicity at serum boric acid levels of 340 µg/mL or less.

6.1.3 **Irritation - Eye**

In humans, acute irritant effects on the eye are well documented in human workers exposed to borates (ECHA/transitional annex XV report (2009a)).

Comment

Acute irritant effects are documented in human workers exposed to sodium borates (EPA, 2004; Wegman et al. 1991; Garabrant 1984, 1985; Woskie et al., 1994, 1998; Cain et al., 2004, 2008). Symptoms include nasal and eye irritation, throat irritations, cough, and breathlessness.

Boric acid exposure was only studied by Garabrant 1984 and Cain et al. 2008. The Garabrant 1984 study did not distiquish which of the two exposures (boron oxide or boric acid) was associated with reported symptoms. Boron oxide reacts exothermically with water to form boric acid suggesting a possible mechanism for boron oxide irritancy. It is believed that these irritant effects are caused by the exothermic hydration of boron oxide to boric acid. Cain et al. (2008) reported a NOAEL for irritation among human volunteers inhaling boric acid of 10 mg/m^3, the highest exposure evaluated for boric acid. The exposure of 10 mg/m^3 evaluated in Cain et al. did not reach a level defined by the investigators as being irritating to the eyes, nose or throat. Furthermore, for any given point in exposure time the dose-response curve had a very low slope, not characteristic of an irritant.

6.1.3 Irritation – Respiratory tract

In acute experimental animal studies (rat) with disodium tetraborate (pentahydrate & decahydrate) and boric acid, the effects observed were ocular and nasal discharge, hunched posture and hypoactivity. In mice, a 20% reduction of the respiratory rate was observed from inhalation of boric acid (300 mg/m3) and it was based on this response concluded that boric acid acts as sensory irritant (ECHA/transitional annex XV report (2009a).

Comment

This information was taken from the Transitional Annex XV report (2009), and does not consider recent studies conducted since publication of the report as reported in the registration dossier for boric acid and sodium borates.

A GLP airway sensory irritation respiratory depression (RD50) study of boric acid and sodium tetraborate pentahydrate (SB) was conducted in male Swiss-Webster mice based on the ASTM E981-04 (2004) standard test method of estimating sensory irritancy of airborne chemicals (Kirkpatrick 2010, Maier et al. 2014). The ASTM E981-04 sensory iritancy test (Alarie assay) has been demonstrated to be a reliable test for estimating sensory irritancy of airborne irritants and RD50s are a basis, at least partially, for OELs by ACGIH (Kuwabara et al. 2007). ECHA guidelines (Chapter R.8) acknowledge the use of the Alarie assay in assessing respiratory irritation.

It was not possible to achieve an aerosol concentration high enough to result in a 50% respiratory depression in mice for boric acid or sodium tetraborate pentahydrate based on the results in the mouse sensory irritation model. The highest concentration of boric acid that was achievable with acceptable control of the aerosol concentration was 1096 mg/m3 with a %RD of 19%. Based on these results, the RD50 is > 1096 mg/m3 for boric acid. The ASTM standard uses the value of 0.03 x RD50 for estimation of threshold limit values (TLV). Alarie et al. (2001) has established that a value of 0.01 x RD50 as the concentration where no sensory irritation would be seen in humans. Therefore, although the highest achievable concentration was below the RD50 value for boric acid, based on the high aerosol concentrations achieved with %RD values below 50%, it is clear that boric acid is not a respiratory irritant or at worst has an extremely low potency as a sensory irritant. Exposure to a mean boric acid concentration of 1096 mg/m3 resulted in a decrease in a 19% reduction in respiratory rate, graded as slight irritation. A 9% reduction in respiratory rate was recorded at an exposure concentration of 221 mg/m3. This response was graded as no irritation (ASTM, 2004).

The RD_{50} for SB was >1704 mg/m^3 when male Swiss-Webster mice were exposed to a dust aerosol of the test substance as a single, 30-minute, head-only exposure. A maximum exposure concentration of 1704 mg/m^3 resulted in a 33% reduction in respiratory rate, graded as moderate irritation. The lowest exposure concentration of 186 mg/m^3 resulted in a respiratory rate reduction of 11%, graded as no irritation.

The practical side of these results is that occupational exposure limit of 10 mg/m^3 total particulate will prevent any sensory irritation in workers.

6.1.3 Irritation – Respiratory Track

In humans, acute irritant effects are well documented in surveys of human workers exposed to boric acid and borates; symptoms include nasal and eye irritation, throat irritation, cough, and breathlessness.

Based on occupational data from boron mining and processing plants, a NOEC value of 0.4 mg B/m3 for acute irritant was established leading to a final NOEC of 0.8 mg B/m3 (The value has to be corrected by a factor 2 as the methods used for exposure measurements underestimated air concentrations). At higher levels, dose-related effects such as nose, eye and throat irritation, sneezing, nose bleeds, coughing and breathlessness, phlegm production and broncho-constriction were observed (ECHA/transitional annex XV report (2009a)).

Overall, boric acid and borates are eye and respiratory tract irritants. In humans, borates act as respiratory sensory irritants, and a NOEC of 0.8 mg B/m3 has been established leading to a DNEL for acute inhalational worker exposure of 0.8 mg B/m3.

Comment

Acute irritant effects are extensively documented in human workers exposed to sodium borates (Wegman et al. 1991; Garabrant 1984, 1985; Woskie et al., 1994, 1998; Cain et al., 2004, 2008). Symptoms include nasal and eye irritation, throat irritations, cough, and breathlessness. However, boric acid exposure was only studied by Garabrant 1984 and Cain et al. 2008. The Garabrant 1984 study did not distiquish which of the two exposures (boron oxide or boric acid) was associated with reported symptoms. Boron oxide reacts exothermically with water to form boric acid suggesting a possible mechanism for boron oxide irritancy. It is believed that these irritant effects are caused by the exothermic hydration of boron oxide to boric acid. Cain et al. (2008) reported a NOAEL for irritation among human volunteers inhaling 10 mg/m^3 boric acid, the highest exposure evaluated for boric acid. The exposures of 10 mg/m^3 evaluated in Cain et al. did not reach a level defined by the investigators as being irritating. Furthermore, for any given point in exposure time the dose-response curve had a very low slope, not characteristic of an irritant.

The transitional Annex XV dossier reports that a LOEC of 0.44mg B/m^3 was derived from Cain et al. (2008). However, the authors of the study clearly state the levels of exposure did not reach the level considered irritating by subjects "…the highest levels studied here lay at the edge of where people would agree that feel in the nose becomes irritating, about 17-18 % carbon dioxide. None of the functions actually reached that concentration, though those for 2.5 mg/m^3 calcium oxide and 10 mg/m^3 sodium borate came close. "

In the Transitional Annex XV Dossier, used Poisson regression analysis of the results from Wegman et al. (1991) was used to estimate a NOEC. However, Wegman et al. did not study worker exposure to boric acid but instead an alkaline dust containing unspecified sodium borates. And sodium borate information cannot be extrapolated to boric acid for irritant responses. While occupational inhalation exposure is often standardized to boron equivalents due to analytical limitations in distinguishing the borate substance in particulate air samples, there is no showing that boron is responsible for any irritant effects.

The Wegman data is based on subjective responses on a severity scale assigned to exposure ranges rather than a specific exposure level and contains no clear dose-response information. There is no way to identify where in this exposure spectrum symptoms occurred. Furthermore, symptoms were also reported in the group of workers not considered to be exposed (office workers), making any estimate of the NOEC unreliable.

6.1.5 Repeated dose toxicity

In rats a NOAEL of 8.8 mg B/kg bw/day was found in a 90-day study in relation to body weight reduction, clinical signs of toxicity, and testicular atrophy.

Comment

One male at 26 mg B/kg bw/day exhibited partial testicular atrophy. However, testicular atrophy is occasionally seen in young and old un-treated Sprague-Dawley rats (Aleman et al., 1998), therefore the partial testicular atrophy was considered an anomaly and was not considered treatment related.

In a subsequent follow-up Sprague-Dawley rat 90-day study on disodium tetraborate decahydrate with the same design, no adverse effects were observed at levels up to 26 mg B/kg bw/day (Weir, 1963).

6.1.8 **Reproduction and Developmental Toxicity**

Based on the identified NOAEL for reproductive toxicity (17.5 mg B/kg bw/day), a DNEL for consumers using an assessment factor of 100 (Interspecies 10, Intraspecies 10) was derived (ECHA/RAC opinion (2010b)): DNEL consumers= 0.175 mg B/kg bw/day

Based upon the identified NOAEL for developmental toxicity (9.6 mg B/kg bw/day corresponding to 55 mg boric acid/kg bw/day), a DNEL for consumers using an assessment factor of 100 (Interspecies 10, Intraspecies 10) was derived (ECHA/ RAC opinion (2010b)): DNEL consumer = 0.096 mg B/kg bw/day

Comment

Some members of the RAC during the tenth meeting of the RAC pointed out that several elements of the risk assessment of boric acid and borate compounds in photographic applications had been over estimated such as the DNEL value and several elements of the exposure worst case scenarios. Considering the toxicokinetic profile or boron and boron compounds it was considered that the 10x10 assessment factor was an over conservative approach and that there were good scientific justifications to derogate from these default values. In fact, WHO had used a 6 (intraspecies) x10 (interspecies) uncertainty factor in deriving its Guidelines for Drinking Water Quality (2003 & 2009) for boron and, based on the same data, EFSA in 2004 had also utilised a combined assessment factor of 60.

However, because a quantitative estimation of the assessment factor to be used in the opinion would require an in-depth assessment of the toxicokinetic information and due to timeline constrains the RAC decided to utilise the 10x10 assessment factors. But the RAC also noted in the final opinion that there are grounds for derogating from the use of default values, and the use of the conservative default value could contribute to an overestimation of the risk (ECHA RAC 2010).

6.1.9 Overall conclusions for boric acid and borates

In terms of developmental toxicity, developmental effects of boron (boric acid) have been examined in experimental animal studies (rat, mice and rabbit) using oral dosing. Developmental effects in terms of visceral and skeletal malformations were observed in a dose and species dependent manner in rats, mice and rabbits, rats being more sensitive than mice and rabbits. A NOAEL of 9.6 mg B/kg bw/day for developmental effects was established in a prenatal rat study using boric acid (identified as the key study). Based on the identified NOAEL value, a DNEL consumer = 0.096 mg B/kg bw/day could be established using an assessment factor of 100. No human data exist with regard to developmental toxicity.

The effects of boric acid and boron compounds on reproduction and development indicate that a classification with Repr. 1B, H360FD (May damage fertility and the unborn child) should be applied for boric acid. This was recently confirmed by RAC in their opinion on proposed harmonized classification and labelling of boric acid (ECHA/RAC opinion (2014)).

Comment

See comments to section 6.1.8 above.

Assessment Factors the General Population

A refinement of the individual assessment factors is presented in the registration dossier based on substance-specific (boron) toxicokinetic (TK) information. The examination of species differences in boron distribution to extravascular fluids and renal elimination served as the basis for the replacement of the default value for interspecies TK subfactor, while critical intraspecies evaluation of the human inter-individual variation of underlying renal clearance mechanism (glomerular filtration rate) served as the basis upon which to replace the default value for the intraspecies TK component (Maier et al. 2014). Because of worker exposure studies, data available on the apparent protective effect of zinc and the intrinsically higher zinc levels in humans, the data show that humans are not more sensitive than laboratory animals.

The data-derived toxicokinetic adjustment factor for boron for human variability was calculated in the US EPA (2004) assessment from data on the variability in glomerular filtration rate (GFR) during pregnancy. GFR was identified as the primary determinant of boron clearance rates. The US EPA (2004) modified the sigma method (Dourson et al., 1998) to calculate the lower bound of risk at 3 standard deviations (SD) with the goal of ensuring adequate coverage of preeclamptic women (the sensitive subpopulation), resulting in a reduction of the intraspecies (i.e., human variability) toxicokinetic adjustment factor.

6.2.1.1 Consumers

Paper wool insulation

Comment

The reference Larsen 2012 directs you to rock wools web site, a competitor of paper wool with a conflict of interest and not a legitimate scientific site for risk assessment information.

Fertilisers

RPA (2008) indicates that fertilisers may contain 10% boron and considers that inadvertent ingestion by the user is unlikely to exceed 100 mg fertiliser per day or 10 mg B/day (corresponding to 0.14 mg B/kg/d).

Comment

Fertilisers for consumer use as concentrated solutions or granules usually contain 0.02% boron and 0.2 ppm boron in the dilute working solution (Austria 2008). The concentration of boric acid in fertiliser rods is <1% (Scotts 2005). Boron is a micronutrient, so concentrated solutions of fertilizer with 10% boron are not available to consumers. According to the Fertilizers Association the majority of fertilizers for soil application are below the specific concentration limit of 0.96% Boron.

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Detergents

Although boric acid/borax are used as stabilisers in liquid fabric detergents, the main exposure to borates from detergents may stem from the use of sodium perborate as bleach in laundry detergents.

Assuming a dermal uptake of 1%, this would lead to a systemic exposure of 0.04 mg B/d (or 0.0006 mgB/kg bw/d).

Comment

Dermal uptake has been shown to be less than 0.5% in human skin and studies using human volunteers as noted under Section 6.1.1.

There is limited use of borates in consumer products in the form of mixtures, such as detergents, where the concentration is low and it leads to consumer RCRs significantly <0.01 (see registration dossiers). Further, REACH Annex XVII limits the sale to consumers of mixtures containing borates above the Specific Concentration Limit (SCL).

6.3.2 Consumers

Food

Further, EFSA (2013) concluded that exposure to boron from its natural occurrence in the diet and from other sources (dietary supplements, food contact materials, feed for food-producing animals, cosmetics, oral hygiene products, etc.) already may lead to an exposure that exceeds the ADI.

Comment

The Panel on Food Additives and Nutrient Sources added to Food (ANS) Panel also concluded that it is unlikely that a regular exceedance of the ADI occurs.

For children and adolescents, at the highest 95th percentile, exposure estimates indicate exceedance of this ADI. However, exposure to boron from its use as a food additive in the form of boric acid and sodium tetraborate in caviar is unlikely to occur on a regular basis. Therefore, the Panel noted that even at high consumption and in consumers only, it is unlikely that a regular exceedance of the ADI occurs.

Photographic applications

The Risk Assessment Committee at ECHA has derived a DNEL value of 0.09 mg B/kg bw/d. In a risk assessment of one specific exposure scenario using boric acid for photographic applications, it was concluded that the DNEL was exceeded, but only when background exposure to boron (from drinking water and food) was also taken into account. Overall, the background exposure to borates may be very close to the DNEL value (and in some cases even above) and thus additional sources from e.g.

cosmetics, dietary supplements, fertilisers, boric acid dust from cellulose insulation, etc. may for some already highly exposed people lead to exceedance of the DNEL value.

Comment

See comment under Section 6.1.8

No exceedances of the DNEL would have occurred had the AF of 60 been used.

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