Committee for Risk Assessment

RAC

Opinion on
new scientific evidence on the use of boric acid and borates in photographic applications by consumers

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Adopted

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OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON NEW SCIENTIFIC EVIDENCE ON THE USE OF BORIC ACID AND BORATES IN PHOTOGRAPHIC APPLICATIONS BY CONSUMERS

Pursuant to Article 77(3)(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation),

the Committee for Risk Assessment (RAC) has adopted an opinion on whether risks arising from the consumer use of :

- Boric acid (CAS No 10043-35-3, EC No 233-139-2)
- Boric acid, crude natural, containing not more than 85 per cent of H_3BO_3 calculated on the dry weight (CAS No 11113-50-1, EC No 234-343-4)
- Diboron trioxide; boric oxide (CAS 1303-86-2, EC 215-125-8)
- Disodium tetraborate, anhydrous; boric acid, disodium salt (CAS No 1330-43-4, EC No 215-540-4)
- Tetraboron disodium heptaoxide, hydrate (CAS No 12267-73-1, EC No 235-541-3)[1]
- Orthoboric acid, sodium salt (CAS No 13840-56-7, EC No 237-560-2)[1]
- Disodium tetraborate decahydrate; borax decahydrate (CAS No 1303-96-4, EC No 215-540-4)
- Disodium tetraborate pentahydrate; borax pentahydrate (CAS No 12179-04-3 EC No 215-540-4)

in photographic applications are adequately controlled.

I. PROCEDURE FOR ADOPTION OF THE OPINION

Following a request from the European Commission, the Executive Director asked RAC to review and evaluate the information relating to the use of the abovementioned substances in photographic applications and to give an opinion whether the risks to consumers are adequately controlled. In cases where the risks are not adequately controlled, RAC was asked to provide indications on additional and precautionary measures required to reduce the possible risk to consumers.

On 4 November 2009 the ECHA Secretariat requested RAC stakeholder observers to provide information relevant for the opinion development by 25 November 2009. No

[1] The opinion does not cover these substances because RAC has received specific indications from industry that they are no longer on the EU market.

information was received. In addition, on 11 November 2009 the ECHA Secretariat requested the European Photo Imaging Association (EPIA[2]) to provide further information to complement the data provided earlier to the Commission and this was provided by EPIA on 19 November 2009. Information was provided to ECHA from Imaging and Printing Association e.V (I & P Europe) on 19 January and then on 4 February 2010. Two further requests were sent from ECHA on 12 February 2010 to further clarify certain aspects of the data to I & P Europe and an expert from Harman Technology Ltd, UK. Both sent their response to the RAC Secretariat on 19 February 2010. Eurometaux provided information in relation to the EASE model and dermal exposure for metals on 13 March 2010.

RAC appointed Annemarie Losert as rapporteur on 17 November 2009, supported by an ad-hoc working group composed of the RAC members: Maria Teresa Borges, Helmut A. Greim, Frank Jensen, Olivier Le Curieux-Belfond, Karen van Malderen and Céu Nunes, and invited experts: Max Kinzl, Umweltbundesamt, Austria and Friederike Neisel, Bundesinstitut für Risikobewertung, Germany.

The RAC opinion was adopted on 29 April 2010.

The RAC opinion was adopted by consensus.

II. OPINION OF RAC

RAC has formulated its opinion on the risk associated with the use of the above listed substances in photographic applications intended to be used by consumers. This was based on the information provided in the mandate, as well as additional information received from industry.

RAC concludes that the use of boric acid and borates in photographic applications does not pose a risk to consumers when no other boron sources are considered. However, as there are more possible sources that contribute to the total boron exposure of consumers, these additional sources have to be considered in the risk assessment of boron compounds. Diet and drinking water represent a considerable part of daily boron exposure for the general public. Other sources, like occupational boron exposure or exposure via other consumer products (e.g. cosmetics) further contribute to boron exposure, but were not evaluated for the present opinion.

For the photographic scenarios in which consumers handle fixers and liquid film developer concentrates the risk is still adequately controlled when exposure via food and drinking water is considered. However, when including exposure via food and drinking water, the present evaluation indicates that risks are not adequately controlled for the specific scenarios based on reasonable worst case assumptions when film developer solutions are prepared from powder formulations and used for tank or tray processing on the same day.

III. SCIENTIFIC GROUNDS FOR THE OPINION

RAC has been requested to evaluate, whether the consumer use of boric acid and borates in photographic applications poses a risk to consumers that is not adequately controlled. This assessment focuses on the exposure and risks resulting from the consumer use of boron containing photochemicals.

[2] During the work on this assessment the two associations EPIA – European Photo and Imaging Association and CIPHO – Chemieverband Imaging, Printing und Photo e.V. have joined forces and are now called I&P Europe – Imaging and Printing Association e.V.

The present evaluation is based on information on use and exposure received from the EPIA (European Photo and Imaging Association), I&P Europe (Imaging and Printing Association), representative Safety Data Sheets, internet search (e.g. web fora) and the Austrian Transitional Dossier on Boric Acid and Disodium Tetraborate Anhydrous (Austria, 2009).

The industry associations EPIA and I&P Europe, as well as the RAC stakeholders were invited to present information on the marketed products for non-professional users. According to this information, boron compounds are used in film developers as well as in film and paper fixers. These photographic products are used by amateur consumers, representing a limited but unknown percentage of the overall population. It has to be noted that EPIA respectively I&P represent only 90% of the European market.

Following the European Commission request, the opinion is targeted to this specific use and does not cover the potential exposure of consumers to other uses of boron compounds. The results of this assessment have been compared and combined with the background exposure of consumers resulting from naturally occurring boron in food and drinking water derived in the Austrian Transitional Dossier, as every consumer is subject to that source of exposure. It should be noted that the figures presented in the Austrian Transitional Dossier (Austria, 2009) have not been evaluated by RAC as assessing this exposure source was not part of the RAC mandate. Other sources (e.g. dermal absorption from cosmetics, oral route from food supplement, dermal or inhalation exposures from biocides used in wood treatment, etc.) were not considered for the present evaluation.

Effect assessment and DNEL derivation

Boric acid and borates are reprotoxic substances that can produce effects on both development and fertility. From the assessment of the available toxicological information RAC concludes that developmental effects, including reduced foetal body weight as well as skeletal and visceral malformations in different species (rat, mouse and rabbit), should be considered as the leading effect for the DNEL derivation. A General Population-DNEL long term systemic of 0.096 mg B/kg bw/day for developmental effects has been used in this assessment. This DNEL was derived using the study with the lowest NOAEL (9.6 mg B/kg bw/day) from an oral developmental study fulfilling the information requirements to evaluate developmental effects (OECD 414, GLP). With regard to developmental effects a single peak exposure can be sufficient to induce effects on the developing foetus when occurring in the appropriate time window of development.

Boron compounds are substances for which refinement of the default assessment factors for inter- and intraspecies variability may be possible, as toxicokinetic differences between species and human individuals seem reduced compared to other substances. However, for a possible refinement of the default assessment factors additional data on toxicokinetic behaviour in rats and a detailed evaluation of the complete available toxicokinetic database would be necessary. Given the limited time available for the present request, the default assessment factors of 10 for extrapolation from rat to human and 10 for intraspecies variability within the general population have been used in the present assessment. The use of this conservative default value could contribute to an overestimation of the risk.

Toxicokinetic assessment and dermal absorption

Boron compounds are readily absorbed orally and by inhalation as demonstrated by numerous studies reporting increased levels of boron in blood, tissues, or urine after exposure via both routes (Austria, 2009). For the present evaluation absorption rates for oral and inhalation route are assumed to be 100%.

RAC has evaluated the available studies on dermal absorption and selected two specific values to be used in the exposure assessment. For dermal contact to dusts and liquid spillages a dermal absorption fraction of 0.5% has been derived from the in vivo part of the study by Wester et al. (1998); as human in vivo studies are most relevant for human risk assessment. The same value was used in the Biocides Report (2009) as well as in the Austrian Transitional Dossier (Austria 2009). From an evaluation of all available data on dermal absorption and other toxicokinetic findings it can be concluded that dermal absorption of boron compounds is rather low and most probably around 0.5%. However, the in vivo study by Wester et al. (1998) has several shortcomings (see Background Document). To cover parts of the resulting uncertainty a value of 0.5% was derived by adding the standard deviation to the mean of the absorbed dose percentage. However, it is also conceivable that absorption could be higher than 0.5%.

Dermal absorption from liquids during continuous exposure is better described by the use of fluxes (permeability (Kp) x concentration (C)) than by using percent absorption. Based on the original data from an infinite dose in vitro study by Wester et al. (1998) a Kp of 2.0×10^{-4} could be derived. This is the mean of four Kp values derived for solutions with different boron concentrations and an exposure duration of 4 hours. The 4 hours time point of the experiment was chosen to avoid an overestimation of dermal absorption, which would be the case when using the 24 hours time point (for details on Kp derivation see Background Document).

The assessment of dermal absorption is based on a poor quality data base. Although an evaluation of the whole data base indicates that dermal absorption through intact skin is low there remains an uncertainty concerning the estimates used, which could lead to both an underestimation and an overestimation of dermal absorption. It has to be noted that absorption through damaged skin is considerably higher.

Exposure assessment

No studies and models are available for the determination of the exposure of non-professionals to photographic chemicals. Two approaches per scenario are presented; the first approach is the “typical case”. It represents the expected, typical exposure level of the scenario referring to values within the given variability of data as well as to standard default values. A “reasonable worst case” (RWC) of the same scenario is also presented in order to combine the worst possibility of each exposure parameter. The use of personal protective equipment (PPE) is not considered for consumers, even if they are recommended by the manufacturer. This is in line with ECHA guidance.

Higher exposures via the use of photochemicals are conceivable (e.g. use of the photochemical products for other purposes than the processing of photographic films), but are not considered as these scenarios would result from unforeseen applications of the products.

The present assessment covers the use of four different photographic products: Scenario A: Use of film developer solutions made from liquid concentrates (max. 0.85% B [3]), Scenario B: Use of film developer solutions made from powder formulations (max. 5.5% B [3]), Scenario C: Use of fixer solutions made from liquid concentrates (max. 0.46% B [3]), Scenario D: Use of fixer solutions made from powder formulations (max. 0.18% B [3]). The derived exposure scenarios describing the application of these products comprise the following tasks:

- Pouring liquid concentrates into container (A1, C1)
- Pouring powder formulations into container (B1, D1)
- Tank processing (A2, B2, C2, D2)
- Tray processing of films (A3, B3, C3, D3)
- Tray processing of papers (C4, D4)

As the development of plane films in trays is time consuming and complex (Scenario A3, B3, C3, D3), this procedure is much less widespread among consumers than the development of films in tanks (Scenario A2, B2, C2, D2) and tray processing of papers (C4, D4). Therefore, combination of scenarios A1+A2, B1+B2, C1+C2+C4 and D1+D2+D4 covering only "preparation of working solutions", "tank processing" and "tray processing of papers" (only relevant for fixers) are expected to comply with the common use pattern of most consumers (see table I).

As a minor group of non-professional users perform tray processing of films, it cannot be excluded that the preparation of solutions, tank and tray processing of films (and papers) are also done on the same day. Therefore, exposure levels of these scenarios have also been derived, although they are expected to be less widespread among the users (see table II).

The presented exposure scenarios are expected to cover the foreseeable consumer uses. However, the use pattern, skills, experience, hygiene of consumers and the boron content of products and working solution can differ significantly and are also partially unknown. Therefore conservative assumptions were necessary to address the lack of particular exposure data, different levels of uncertainties and expected variation of relevant exposure parameters. The background document includes a more detailed uncertainty analysis.

Risk characterisation

Risk characterisation ratios (RCRs) have been obtained by comparing exposure levels to the General Population-DNEL long term systemic of 0.096 mg B/kg bw/day for developmental effects. Risk characterisation ratios of combined exposure scenarios (which are expected to be performed on the same day) are presented below.

All typical case RCR values are 7 to 100 times lower than 1 and all the realistic worst-case RCR values are still clearly below 1. The derived scenarios for the use of boric acid and borates in photographic processing represent no risk, if only exposure from photographic applications and no other boron sources are considered.

[3] Maximum boron concentrations of the respective products as supplied, referring to data provided by EPIA or I&P.

Table I: Risk characterisation ratios of combined scenarios covering the most widespread applications

Scenario	RCR[1] [ ] Typical	RCR[1] [ ] RWC
Film developer: liquid concentrates A1 + A2 Preparation + tank processing	0.07	0.15
Film developer: powder formulations B1 + B2 Preparation + tank processing	0.12	0.69
Fixer: liquid concentrates C1 + C2 + C4 Preparation + tank processing + tray processing of papers	0.04	0.20
Fixer: powder formulations D1 + D2 + D4 Preparation + tank processing + tray processing of papers	0.01	0.13

[1]Referring to a General Population-DNEL long term systemic of 0.096 mg B/kg bw/d

Table II: Risk characterisation ratios of combined scenarios including tray processing of films

Scenario	RCR[1] [ ] Typical	RCR[1] [ ] RWC
Film developer: liquid concentrates A1 + A2 + A3 Preparation + tank processing + tray processing of films	0.08	0.22
Film developer: powder formulations B1 + B2 +B3 Preparation + tank processing +tray processing of films	0.13	0.78
Fixer: liquid concentrates C1 + C2 + C3 Preparation + tank processing + tray processing of films	0.04	0.20
Fixer: powder formulations D1 + D2 + D3 Preparation + tank processing + tray processing of films	0.01	0.13

[1]Referring to a General Population-DNEL long term systemic of 0.096 mg B/kg bw/d

However, consumers are also exposed to other boron sources, with boron uptake via diet and drinking water being the most relevant exposure source. The exposure estimates for food and drinking water derived in Austria (2009) were applied to assess this contribution to boron exposure of consumers using photochemicals. Other sources of boron exposure like other consumer products or occupational exposure were not evaluated, but would further contribute to total boron exposure.

The combination of the photographic application scenarios and the background exposure levels via food and drinking water suggest that RCRs below 1 are expected for most combined exposure scenarios (see tables XVIII and XIX of the Background Document). Only for the combined exposure scenarios based on worst-case assumptions in the specific case of consumers preparing solutions from powder film developer formulations and using tank or tray processing on the same day (Scenarios B1+B2 and B1+B2+B3) the

RCR values will be above 1 when combined with typical and RWC background exposures, suggesting a potentially unacceptable risk (combined RCRs of 1.17 and 1.26, with a contribution of 0.48 from typical food and drinking water exposure, and combined RCRs of 1.38 and 1.47, with a contribution of 0.69 from RWC food and drinking water exposure).

The combination of background exposures with combinations of RWC scenarios of A, C, and D would result in RCRs above 1. However, the likelihood that several boron containing photographic chemicals, e.g. film developer and fixer, are used on the same day is unknown as there are only a few boron containing products on the market.

It has to be noted that many of the applied approaches in the present evaluation rely on conservative assumptions due to uncertainties and data gaps. The conservatism applied could be replaced by a refined assessment, if adequate information and time were available.

Possible risk management measures

At the present stage, risk management measures (RMM) should be considered in order to achieve acceptable risks for specific amateur uses of photochemicals. The only scenarios for which unacceptable risks were identified in the present evaluation were those in which powder formulations of film developers were applied (considering boron exposure via diet and drinking water).

Possible measures to reduce the risk could be the substitution of powder formulations by liquid formulations or the requirement to only supply the general public with products in the form of granulated powder. It has to be noted that feasibility and effectiveness of this measure to reduce boron exposure of consumers was not evaluated for the present assessment. A replacement by boron-free products seems possible and should therefore be considered as another option.

The products containing film developers in powder form are currently the only photographic consumer products with boron concentrations exceeding the specific concentration limit of 1% boron (this equals e.g. 5.5% boric acid) for classification and labelling of mixtures as toxic to reproduction (Category 2, R60, 61). Labelling of products can be regarded as a RMM, but as for the application of PPE, it cannot be guaranteed that the labelling of a product triggers the appropriate behaviour of the consumer.

The introduction of a concentration limit for the use of boron compounds supplied in powder products would be another RMM option.

Conclusions

RAC concludes that the use of boric acid and borates in photographic applications in itself does not pose a risk to consumers. However, as there are more possible sources that contribute to the total boron exposure of consumers, these additional sources have to be considered in the risk assessment of boron compounds.

Food and drinking water represent a significant source of exposure to which the general public is exposed on a daily basis. When data on exposure through diet and drinking water is applied as estimated by Austria (2009) an RCR above 1 is obtained for the scenarios based on reasonable worst-case parameters in the specific case of consumers which may prepare solutions from powder formulations for film developers and use them for tank or tray processing of film on the same day.

The identified risk partly results from conservative assumptions due to data gaps with regard to use pattern, consumer behaviour and boron concentrations in future products and products of companies not covered by the information presented by EPIA and I&P. Further, it has to be noted that a detailed evaluation of the toxicokinetic data for boron compounds in rats and humans may result in a higher DNEL than applied for the present risk characterisation.

In contrast it has to be considered that other sources of boron exposure (like other boron-containing consumer products, or occupational exposure) were not considered in the present evaluation, but would further contribute to the total boron exposure, and thus to the risk for consumers.

ANNEXES

Annex 1	Background document
Annex 2	Request from the Commission to ECHA (ENTR/G2/GL/sik D(2009)32530
Annex 3	Decision by the Executive Director of ECHA (ED/45/2009) – the mandate
Annex 4	List of Information provided by Industry

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