Risk Management Option Analysis Conclusion Document

Substance Name: Borates including boric acid and diboron trioxide:

EC name	Index No	EC No	CAS No
boric acid	005-007-00-2	233-139-2 234-343-4	10043-35-3 11113-50-1
diboron trioxide	005-008-00-8	215-125-8	1303-86-2
disodium tetraborate, anhydrous; boric acid, disodium salt	005-011-00-4	215-540-4	1330-43-4
tetraboron disodium heptaoxide, hydrate		235-541-3	12267-73-1
orthoboric acid, sodium salt		237-560-2	13840-56-7
disodium tetraborate decahydrate	005-011-01-1	215-540-4	1303-96-4
disodium tetraborate pentahydrate	005-011-02-9	215-540-4	12179-04-3
disodium octaborate anhydrous	005-020-00-3	234-541-0	12008-41-2
disodium octaborate tetrahydrate		234-541-0	12280-03-4

Authority: Germany

Date: 18 January 2021

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 1: REACH and CLP processes for Borates covered in this RMOA.

Substance	RMOA	REACH Processes						Harmonised C&L
		Evaluation			Authorisation		Restriction	
	other than present	Compliance check	Testing proposal	CoRAP / Substance Evaluation	Candidate List	Annex XIV	Annex XVII Entry 30	Annex VI (CLP)
Boric acid					x		x	x
Diboron trioxide					x		x	x
Disodium tetraborate, anhydrous					x		x	x
Tetraboron disodium heptaoxide, hydrate					x		x	x
Orthoboric acid, sodium salt							x	x
Disodium tetraborate decahydrate					x		x	x
Disodium tetraborate pentahydrate					x		x	x
Disodium octaborate (anhydrous / tetrahydrate)	x				x		x	x

Harmonised Classification and Restriction

All borates covered in this RMOA have a harmonised classification as toxic to reproduction for both developmental and fertility effects, i.e. Repr. 1B (H360FD) according to Annex VI of Regulation (EC) No 1272/2008 (CLP).
Due to Repr. 1B classification, Entry 30 of Annex XVII to REACH applies to borates covered in this RMOA.

Authorisation and Candidate List for authorisation

With the exception of orthoboric acid, sodium salt all borates covered in the current RMOA were identified as SVHC and are listed on the Candidate list for authorisation. SE plans to submit an SVHC-dossier for orthoboric acid, sodium salt to ECHA. For the time being, none of the borates covered here are currently under authorisation (listed in Annex XIV).

The borates addressed in this RMOA are used in various preparations and articles intended for consumer use. Several of these uses are covered by sector-specific legislations listed below. For all consumer uses falling within the regime of these sector-specific legislations no additional in depth risk assessment has been carried out and would be outside the scope of this RMOA.
Sector-specific legislations for borates:

- Biocidal products - Regulation (EU) No 528/2012
- Cosmetic products- Regulation (EC) No 1223/2009
- Fertilisers - Regulation (EU) No 2019/1009
- Food additives - Regulation (EU) No 1129/2011
- Food Supplements - Regulation (EC) No 1170/2009
- Food Contact Materials - Regulation (EC) No 1935/2004 & (EU) No 10/2011
- Medical Devices - Regulation (EU) 2017/745
- Medicinal Products - Regulation (EC) No 726/2004
- Drinking water - Council Directive 98/83/EC
- Toys - Directive 2009/48/EC

2. CONCLUSION OF RMOA

The initial concern leading to the RMOA related to borate compounds in consumer products was triggered by frequent RAPEX alerts concerning toy slimes with high boron migration rates and resulting possible health hazards. However, boric acid and borates are also widely used in other mixtures and articles intended for consumer use.

All borates covered in this RMOA are classified as toxic to reproduction for both, developmental and fertility effects, i.e. Repr. 1B (H360FD) according to Annex VI of Regulation (EC) No 1272/2008 (CLP). This RMOA evaluates potential health risks for consumers through exposure to boric acid and borates for toy slime or other consumer products and assesses whether additional regulatory measures are required.

In addition to toy slimes, the following uses with relevant and potentially high consumer exposure were identified: spot remover sprays, automotive fluids and micronutrient fertilisers. The exposure estimates elaborated within this RMOA are calculated based on products with a total concentration of 0.3% (w/w, in mixtures) for boric acid and borates, assuming that the envisaged revision to the GCL of ≤ 0.3% (w/w) for substances classified as Repr. 1B under CLP Regulation is already in place. This approach identified that none of the above mentioned consumer products will raise a concern yielding inacceptable risks. However, risks may arise for toy slime from non-compliant products and for DIY-slime.

Exposure calculations for toy slime (which is a mixture under REACH) revealed no expected exceedance of the DNEL when the toy slime is compliant with the Toy Safety Directive, even taking natural background of boron via food and drinking water into account. Nevertheless, an emanated risk from non-compliant toy slimes with high boron migration has been demonstrated. A restriction under REACH would not resolve the issue of non-compliance with the Toy Safety Directive and therefore is considered of no additional advantage. Thus, there is currently no indication for further regulatory measures, but continued and potentially enhanced monitoring seems crucial to maintain and guarantee product compliance and prevent health risks for children.

For DIY-slime, there is no adequate regulatory measure to control the risk as the use of self-prepared borax[2] solutions or the use of consumer products with an originally different purpose of use (mixtures such as laundry detergents or contact lens fluids), since the

[2] Regulatory process name: Borax ($B_4Na_2O_7*10H_2O$)

production of DIY-slime constitutes a misuse. From a regulatory perspective, there is currently no adequate measure to control the identified risks of DIY-Slime. After the application of the GCL of 0.3% (w/w) under CLP Regulation for the total amount of boric acid and borates has entered into force and Entry 30 of REACH Annex XVII is updated accordingly, placing on the market or use of substances as such, as constituents of other substances or in mixtures at concentrations of more than 0.3% (w/w) for supply to the general public will be prohibited (with the exemption of medical devices such as contact lens fluids which, hence, need to be assessed under the Medical Device Regulation). In order to limit risks from substances or mixtures containing more than 0.3% boron compounds, monitoring activities may be needed. Moreover, an increased awareness of the general public about the potential risks of DIY-slime should be sought through better information.

In this regard, it is noteworthy that there are increasing cases reported of induced hand dermatitis, skin burns and even allergic contact dermatitis after contact with DIY-slimes (Aerts et al., 2018; ANSES, 2018a; Gittler et al., 2018). These effects are mainly related to other ingredients such as fragrances or preservatives and not the borates covered in this RMOA. However, this demonstrates once more the importance to inform consumers about the risks related to DIY slimes e.g. through press releases or notifications (as done by the French National Institute for Consumer Safety (ANSES, 2018a; ANSES, 2018b; ANSES, 2018c) or the Belgian Anti-poison Centre (Belgisch Antigifcentrum)).

Overall, this RMOA concludes that no further regulatory actions for the substances in scope are required, if the anticipated revision of the concentration limits for boric acid and borates will be enforced. This action will already result in an enhanced protection of consumers through reduced exposure levels and the phase-out of products with high boron content. It should also impact DIY-slime preparations, since the supply of consumers with pure boric acid and borates as well as mixtures containing in total more than 0.3% (w/w) of the substances within the scope of this RMOA will be an infringement of the restriction in Annex XVII, Entry 30 of the REACH Regulation. In general, a continued and potentially enhanced monitoring is advised.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	(X)*
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	(X)
No action needed at this time	X

*SE has already published their intention to submit a SVHC dossier.

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

The Danish EPA identified boric acid and borates as eye and respiratory irritants and concluded in their evaluation of the available studies that criteria for classification as Eye Irrit./Dam. as well as STOT SE3 (H335: May cause respiratory irritation) are fulfilled. However, generic classification limits for mixtures according to CLP (with >10%

(Eye Irrit. 2), >3% (Eye Dam. 1), and >20% (STOT SE3)) are far above generic concentration limits of >0.3% which apply due to Repr. 1B classification and REACH Annex XVII Entry 30 currently discussed as part of the draft 17th Amendment to the CLP Regulation. Thus, classification for eye/respiratory irritation may not result in a higher level of protection and is in the remit of the registrants.

It is therefore not proposed to prepare an additional CLH Dossier.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

All boron compounds covered in this RMOA with the exception of orthoboric acid, sodium salt are identified as SVHC due to the Repr. 1B classification and are included on the Candidate List for authorisation. So far, orthoboric acid, sodium salt is not registered under REACH. However, in principle, it could serve as substitute for any of the other borates covered in this RMOA and thus SVHC identification would be beneficial to prevent regrettable substitution.

SE CA plans to submit an SVHC-dossier for orthoboric acid, sodium salt to ECHA.

Moreover, borates without a harmonised classification as Repr. 1B but with potential to release boric acid/bioavailable boron in a similar manner as the borates covered in this RMOA could be seen as potential regrettable substitutes and should undergo a thorough hazard evaluation and, if indicated, classification before being used in consumer products.

It is therefore concluded, that no further action is needed.

3.3 Restriction under REACH

In the RMOA it was identified that none of the above mentioned consumer products will raise a concern yielding inacceptable risks. However, risks may arise for toy slime from non-compliant products and for DIY-slime.

A restriction under REACH would not resolve the issue of non-compliance with the Toy Safety Directive and therefore is considered of no additional advantage.

3.4 Other Union-wide regulatory measures

-

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Related to toy slimes a continued and potentially enhanced monitoring seems crucial to maintain and guarantee product compliance and prevent health risks for children playing with toy slime.

In order to limit risks from substances or mixtures containing more than 0.3% (w/w) boron compounds, monitoring activities may be needed as well, after the generic concentration limits will apply.

An increased awareness of the general public about the potential risks of DIY-slime should be sought through better information.

5. NO ACTION NEEDED AT THIS TIME

There is no need for additional EU-wide regulatory action.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

-