

## COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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**Last data extracted on 10.05.2023**

**Substance name: dipotassium tetraborate**

**CAS number: 1332-77-0**

**EC number: 215-575-5**

**Dossier submitter: Sweden**

### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
20.04.2023	Germany		MemberState	1
Comment received				
SID: Table 1: a boron atom in the structural formula is missing. At the current stage it looks like the structure comprises a C-atom, instead.				

### TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
05.05.2023	Belgium	European Borates Association	Industry or trade association	2
Comment received				
<p>The European Borates Association (EBA) accepts that there is a reproductive effect of certain boron compounds in laboratory animals under test conditions and that read across between boric acid and the substance is applicable. However, the EBA questions the relevancy of these data to consider the substance as meeting the classification and labelling criteria of Category 1B as is proposed in this CLH Report. The EBA is of the view that a Repr. Category 2 H361d classification is more justified than a Category 1B H 360 FD. Secondly, the CLP Regulation provides that weight of evidence should be used to determine the category of classification, and this evaluation is missing from the CLH Report. Finally, we agree with the proposal from the Dossier Submitter to assign the note 11 (additivity note) to the substance.</p> <p>See the attachment for more detailed comments</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment EBA comments on 10 CLH boron compounds.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
07.03.2023	Netherlands	<confidential>	Company-Manufacturer	3

Comment received
<p>I would like that the possibility is evaluated to change the wording of "Note 11" Boron containing substances come in a large range of boron contents (from 1 to ca. 20%) in the CAS and REACH database. As the reprotoxic effect is based on actual bioavailable boron contents, one could argue that if an SCL is indicated this should not be substance weight% based but related to the actual %boron in the substance or mixture. That might also take in account the boron concentration differences between for example the tetraborate anhydrous and any hydrates formed in solutions.</p> <p>Thus allowing a more toxicology and health approach vs simple additivity of the components.</p>

Date	Country	Organisation	Type of Organisation	Comment number
20.04.2023	Germany		MemberState	4

Comment received
<p>Fertility</p> <p>The proposed classification of dipotassium tetraborate as Repr. 1B, H360F, with a GCL due to medium potency is supported.</p> <p>No studies with the dipotassium tetraborate itself are available.</p> <p>Available read-across studies for this endpoint include studies with boric acid and disodium tetraborate decahydrate (borax), both already classified as Repr. 1B, H360FD. The studies in different species indicate that boron severely impairs sexual function and fertility predominantly through an effect on the testes (e.g. testes atrophy, reduced sperm count, viability and motility). In addition, more recent studies confirm these effects. The available human data, which do not show adverse effects, do not contradict the animal data, because the daily exposure to boron was far below the NOAEL/LOAEL in animal studies.</p> <p>Development</p> <p>The proposed classification of dipotassium tetraborate as Repr. 1B, H360D, with a GCL due to medium potency is supported.</p> <p>As with the fertility endpoint, no studies with dipotassium tetraborate itself are available. The classification is solely based on the read-across to boric acid and borax. These substances induced developmental abnormalities (malformations) in different species and are already classified as Repr. 1B, H360D.</p> <p>A recent PNDT study with boric acid (Pleus, 2018) showed a reduction in mean foetal body weight. However, this study has only been evaluated as an additional study. The doses resulting in significant lower foetal weights are below the LOAEL for developmental abnormalities observed in other studies, however, they do support the GCL derived from previous studies.</p> <p>Therefore, criteria for classification of dipotassium tetraborate as Repr. 1B, H360FD, are considered fulfilled.</p> <p>The GCL of 0.3 % is based on read-across from boric acid (lowest ED10/LOAEL) and adjusted for boron equivalents.</p> <p>In addition, there is agreement with no classification for adverse effects on or via lactation.</p>



PUBLIC ATTACHMENTS

1. EBA comments on 10 CLH boron compounds.pdf [Please refer to comment No. 2]