

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 octaborate

CAS number: 12008-39-8

EC number: -

Dossier submitter: Sweden

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
20.04.2023	Germany		MemberState	1

Comment received

Fertility

The proposed classification of dipotassium octaborate as Repr. 1B, H360F, with a GCL due to medium potency is supported.

No studies with dipotassium octaborate itself are available

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.

Development

The proposed classification of dipotassium octaborate as Repr. 1B, H360D, with a GCL due to medium potency is supported.

As with the fertility endpoint, no studies with dipotassium octaborate 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.

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.

Therefore, criteria for classification of dipotassium octaborate as Repr. 1B, H360FD, are considered fulfilled.

The GCL of 0.3 % is based on read-across from boric acid (lowest ED10/LOAEL) and adjusted for boron equivalents.

In addition, there is agreement with no classification for adverse effects on or via lactation.

Date	Country	Organisation	Type of Organisation	Comment number
05.05.2023	Belgium	European Borates Association	Industry or trade association	2

Comment received

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.

See the attachment for more detailed comments

ECHA note – An attachment was submitted with the comment above. Refer to public attachment EBA comments on 10 CLH boron compounds.pdf

PUBLIC ATTACHMENTS

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