

## COMPILED COMMENTS ON CLH CONSULTATION

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### Last data extracted on 24.10.2023

**Substance name: ulexite (CaNaH<sub>12</sub>(BO<sub>3</sub>)<sub>5</sub>.2H<sub>2</sub>O) [1] ulexite (CaNaH<sub>12</sub>(BO<sub>3</sub>)<sub>5</sub>.2H<sub>2</sub>O), calcined [2]; colemanite (CaH(BO<sub>2</sub>)<sub>3</sub>.2H<sub>2</sub>O) [1] boron calcium oxide (B<sub>6</sub>Ca<sub>2</sub>O<sub>11</sub>), hydrate (1:5) [2] colemanite, calcined [3]; tincalconite (B<sub>4</sub>Na<sub>2</sub>O<sub>7</sub>.5H<sub>2</sub>O)**  
**CAS number: 1319-33-1 [1] 92908-33-3 [2]; 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3]; 12045-88-4**  
**EC number: - [1] 296-662-5 [2]; - [1] - [2] 296-640-5 [3]; -**  
**Dossier submitter: Sweden**

### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.10.2023	France		MemberState	1
Comment received				
<p>The read-across approach for reproductive and developmental toxicity was evaluated by the DS. Despite the lack of studies on borate minerals for toxicokinetic data and reproductive toxicity properties, the read-across is considered acceptable with high confidence from previously evaluated boric acid and inorganic borates.</p> <p>As the water solubility of borate minerals are available in this report, they are similar for all substances tested and for boric acid under simple simulated physiological conditions. Thus, extrapolation to boric acid and borate salts is warranted for both toxicokinetic properties and adverse effects on sexual function and fertility and on the development using boron (B) equivalents.</p>				

### TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
13.10.2023	Germany	<confidential>	Company-Downstream user	2
Comment received				
<p>Dear all,</p> <p>We wanted to draw RAC's attention to several points we feel have been neglected in the CLH report on the classification on several borate minerals as toxic for the reproductive system, cat. 1B.</p> <p>The classification proposal is based on read across from boric acid and borax. In the justification for action (section 4), it is stated that this read across is justified due to the formation of boric acid after oral exposure of the borate minerals. However, we would like to point out that the solubility and therefore also the bioavailability of borate substances may differ tremendously depending on the involved cations and crystal structure as well as</p>				

the amount of crystal water. This is also a reason for partially huge differences in given values for the solubility of the same substance in different sources. The values cited in section 7 in the CLH report from Schubert at al. are in comparison to other literature including standard books like the CRC Handbook for Chemistry and Physics or manufacturer's information (partially also cited in section 7) generally higher.

While boric acid and sodium borates in general exhibit quite good solubility in water at neutral or low pH, this is not true for all the boron minerals proposed for classification. As already listed in the CLH report, tincalconite's solubility is comparable to that of boric acid. Ulexite and colemanite, however, are not readily soluble in water at biologically relevant temperatures. There are many publications on the bioavailability of different boron compounds for plants as boron plays an important role as micronutrient. Only above ~ 60 °C, significant amounts of these minerals may dissolve which is not relevant for an effect in the human body. At ambient conditions, the availability is much lower. Therefore, these publications suggest that ulexite and colemanite also have a significantly lower dissolution rate in the human body.

A read across from readily soluble compounds to only partially soluble in case of ulexite or almost insoluble compounds in case of colemanite may lead to false conclusions. Therefore, we kindly ask the RAC members to thoroughly investigate relevant biological concentrations in case of exposure under reasonable scenarios for the each substance individually and to consider a classification into category 2 if there are doubts on effects at the respective concentrations.

Date	Country	Organisation	Type of Organisation	Comment number
05.10.2023	Germany		MemberState	3
Comment received				
The proposed classification as Repr. 1B for the borate minerals ulexite, colemanite and tincalconite is supported by the DE CA. The classification for reproductive toxicity following oral exposure is based on a read-across approach from inorganic borates (borax or disodium tetraborate decahydrate) and boric acid, and justified on the basis of their common behaviour in aqueous media.				

Date	Country	Organisation	Type of Organisation	Comment number
13.10.2023	France		MemberState	4
Comment received				
FR supports the classification proposal Repr. 1B, H360FD.				