

Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

**perboric acid ($\text{H}_3\text{BO}_2(\text{O}_2)$), monosodium salt
trihydrate [1]; perboric acid, sodium salt,
tetrahydrate [2]; perboric acid ($\text{HBO}(\text{O}_2)$),
sodium salt, tetrahydrate; sodium peroxoborate,
hexahydrate [3]**

EC Number: 239-172-9 [1]; 234-390-0 [2]
CAS Number: 13517-20-9 [1]; 37244-98-7 [2];
10486-00-7 [3]

CLH-O-0000007161-83-01/F

Adopted
15 September 2022

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON PERBORIC ACID (H₃BO₂(O₂)), MONOSODIUM SALT TRIHYDRATE [1]; PERBORIC ACID, SODIUM SALT, TETRAHYDRATE [2]; PERBORIC ACID (HBO(O₂)), SODIUM SALT, TETRAHYDRATE; SODIUM PEROXOBORATE, HEXAHYDRATE [3]

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

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**Substance name: perboric acid (H₃BO₂(O₂)), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid (HBO(O₂)), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3]
**EC number: 239-172-9 [1]; 234-390-0 [2]
 CAS number: 13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]
 Dossier submitter: Sweden****

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19.01.2022	Germany		MemberState	1
Comment received				
<p>The DE CA supports to merge Index No. 005-018-00-2 & Index No. 005-018-01-X.</p> <p>According to table 5 the entry "[containing less than 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]" will be removed from the identification. The specification "[containing greater or equal than 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]" (Index No 005-018-01-X) seems to remain, as it is not mentioned in the section "remove". Therefore, the merged entry should comprise the aforementioned specification or it should be named in section "remove" as well.</p> <p>In addition, it is proposed to consider including the category "(dusts and mists)" behind "ATE = 1.16 mg/L" in the proposed Annex VI entry.</p> <p>Moreover, the report does not comprise any information on the physico-chemical properties.</p>				
Dossier Submitter's Response				
<p>Merging entries</p> <p>Thank for supporting the merging of Index No. 005-018-00-2 & Index No. 005-018-01-X.</p> <p>Table 5</p> <p>Thank you for pointing to the editorial mistakes in Table 5. The corrections can be seen highlighted in yellow below in table 5 in Appendix 1.</p>				

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Physicochemical properties

There is only a Reach registration available for Perboric acid, sodium salt, EC number: 234-390-0, CAS number: 11138-47-9 where there is some information on the physicochemical properties of PBS-1 and PBS-4. There is also some information from the *SCCS Opinion on sodium perborate and perboric acid (2010)* and the *European Risk Assessment Report on perboric acid, sodium salt (CAS 11138-47-9)(2007)* (both references included in the CLH-reports) on the per(oxo)borates, including sodium peroxometaborate. The data, when found in all three information sources, appears to be consistent. Please see compiled relevant information on physicochemical properties of sodium peroxometaborate, PBS-1 and PBS-4 in the table below.

Substance name	Sodium peroxometaborate	perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid (HBO(O ₂)), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4]	perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid (HBO(O ₂)), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3]
CAS number	7632-04-4	11138-47-9 [1]; 12040-72-1 [2]; 10332-33-9 [3]; 15120-21-5 [4]	13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]
EC number	231-556-4	234-390-0 [1]; 234-390-0 [2]; 239-172-9 [4]	239-172-9 [1]; 234-390-0 [2]
Molecular formula	NaBO ₃	B ₂ H ₄ O ₈ Na ₂	B ₂ H ₄ O ₈ Na ₂ .6H ₂ O
Molecular weight	81.8 g/mol	199.6 g/mol	307.6 g/mol
Boron content	13,2%	10,8%	7,0%
Physical form	Solid white amorphous powder	Solid white crystal	Solid white crystal
Melting point	63 °C	Decompose >50 - >180°C	Ca 60-65,5 °C
Boiling point	no information available	decomposition	decomposition
Water solubility	21,5 g/L	15-16 g/L	23 g/L
Dissociation constant	Not applicable due to decomposition	Not applicable due to decomposition	Not applicable due to decomposition
Partition coefficient	no information available	Not applicable (analytical difficulties)	Not applicable (analytical difficulties)

RAC's response

RAC thanks the Dossier Submitter for correcting the editorial mistakes and for providing the phys chem properties of the substances. The adapted Table from the Annex is included in the draft opinion.

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TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
20.01.2022	France		MemberState	2

Comment received

Perboric acid, sodium salt tetrahydrate (PBS-4) has a harmonised classification as toxic to reproduction for developmental effects and fertility effects: Repr. 1B (H360Df). Moreover, it has SCLs for adverse effects on sexual function and fertility and for adverse effects on the development of the offspring (at 14% and 10-14%, respectively) that were established based on the toxicity of the boron moiety (B) using an approach proposed by BauA (1998). This method has since been reassessed and the RAC removed the SCLs based from it and concluded on the harmonisation of GCL 0.3% w/w for boric acid and six other sodium borates that have a harmonised classification as Repr. 1B in 2019.

FR agrees with the classification proposed and comes to the same conclusion about the allocation of potency of PBS-4 as medium, GCL of 0.3% for development and fertility.

Page 54, table 30: we cannot find the same ED10 for the developmental effects of PBS-4 presented in the table 30. Indeed, by applying the method presented in the CLP guidance (2017) page 409, section 3.7.2.6.3.3. we obtain different results :

Live foetus weight : ED10 = 271.72 mg PBS-4/kg bw/day

Litter weight : ED10 = 202.68 mg PBS-4/kg bw/day

Could you please re-check your calculations? These results do not change the allocation of potency expected for PBS-4.

Dossier Submitter's Response

Thank you for your support.

We agree that there are mistakes regarding ED10 in table 30 (please see corrections in the table below). As you point out, the corrected ED10 values (calculated according to CLP guidance (2017)) do not change the potency group allocation of PBS-4.

Developmental effects	Dose levels (mg PBS-4/kg bw/day)				ED10 (linear interpolation of available doses)		Allocation of potency group*
	0	100	300	1000	(mg PBS-4/kg bw/day)	mg B/kg bw/day	
Live foetus weight (g)	3.69	3.57	3.28	2.4	127.5 271.7	9 19	Medium, GCL of 0.3%
Litter weight (g)	54.97	52.62	46.49	32.52	197.2 202.7	13.8 14.2	Medium, GCL of 0.3%
Post-implantation loss (%)	2.91	2.39	13.54	15.2	288.8	20.2	Medium, GCL of 0.3%
LOAEL for developmental effects					300	21	Medium, GCL of 0.3%

RAC's response

RAC thanks the Dossier Submitter for correcting the ED10s.

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Date	Country	Organisation	Type of Organisation	Comment number
19.01.2022	Germany		MemberState	3
Comment received				
<p>Fertility:</p> <p>The DE CA supports the classification of sodium per(oxo)borate tetrahydrate (PBS-4) as Repr. 1B, H360F based on both a read-across to boric acid and supporting evidence from a 28-day limit test performed with PBS-4.</p> <p>The DE CA agrees that the read across to boric acid is justified due to the available toxicokinetic information for per(oxo)borates and boric acid as well as the information that the main species in physiological solutions of per(oxo)borates at neutral and acidic pH is boric acid.</p> <p>In 2014, the Committee for Risk Assessment (RAC) concluded in its opinion on boric acid that a classification as Repr. 1B for fertility effects, H360F is justified.</p> <p>It is further agreed that the available 28-day limit test with PBS-4 alone is considered insufficient for the purpose of classification. The results from the study (decreased absolute testes weight, testicular focal tubular atrophy and inhibition of spermiation) together with read-across data on animal studies with boric acid, however, provide clear evidence of an adverse effect on fertility of PBS-4.</p> <p>Fertility- SCL:</p> <p>RAC has concluded on harmonisation of GCL values to 0.3% w/w for boric acid. As the available data on per(oxo)borates were not considered robust enough in order to derive an ED10 by the DS, DE CA agrees that read-across data on boric acid (based on the calculated percentage of boron; ED10 of 17.5 mg B/kg bw/d) can be used for PBS-4. Thus, PBS-4 is considered to belong to the medium potency group with a GCL of 0.3% w/w and the proposed removal of the current specific concentration limit is supported.</p> <p>Developmental effects:</p> <p>Based on results of a reliable prenatal developmental toxicity study (OECD TG 414, GLP) with PBS-4 the DE CA supports to retain the existing classification Repr. 1B, H360D as there is clear evidence of structural abnormalities and malformations.</p> <p>The DE CA further agrees that due to similar malformations observed after PBS-4 and boric acid exposure the data support that the read across is justified between the two substances.</p> <p>Developmental effects- SCL:</p> <p>It is not possible to derive an ED10 due to the low incidences of malformations observed. Therefore, DE CA supports the SCL calculation for PBS-4 based on the LOAEL for developmental effects. As the LOAEL is estimated to be 300 mg/kg bw/d PBS-4 belongs to the medium potency group, for which a GLC of 0.3% w/w applies. Thus, the proposed removal of the specific concentration limit in the current Annex VI entry is supported.</p>				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
RAC agrees.				

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OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
20.01.2022	France		MemberState	4
Comment received				
<p>Acute inhalation toxicity: We agree that the use of the thoracic fraction approach is not the most appropriate for classification, as the OECD technical guidelines for acute inhalation toxicity recommend using aerosols with a mass median aerodynamic diameter (MMAD) ≤4 µm and a geometric standard deviation (GSD) in the range of 1.0 to 3.0, so particles can reach all regions of the respiratory tract. Moreover studies show that hydrogen peroxide released by hydrolysis contributes mainly of the acute toxicity of per(oxo)borates. Therefore, the acute toxicity of per(oxo)borates would not be due to the particle diameter size.FR agrees that the cut-off value of 50 µm for particle size should be removed.</p> <p>The classification Acute tox 4 H332 and the ATE of 1.16 mg/L is supported.</p>				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
RAC has no further comments.				

Date	Country	Organisation	Type of Organisation	Comment number
19.01.2022	Germany		MemberState	5
Comment received				
<p>Acute oral toxicity: The DS's proposal of no classification for acute oral toxicity for PBS-4 is supported.</p> <p>Acute dermal toxicity: The DS's proposal of no classification for acute dermal toxicity for PBS-4 is supported.</p> <p>Acute inhalation toxicity: The DE CA supports the removal of the asterisk (*) indicating minimum classification and the setting of the ATE value of 1.16 mg/L based on the acute inhalation toxicity study (Study Report 1987c) considered reliable and appropriate by the DS.</p>				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
RAC has no further comments.				

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APPENDIX 1

Table 5: Proposed harmonised classification according to the CLP criteria

	Index No.	International Chemical Identification	EC No.	CAS No.	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entries	005-018-00-2	perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O ₂)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] 231-556-4 [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B STOT SE 3 Eye Dam. 1	H360Df H335 H318	GHS05 GHS08 GHS07 Dgr	H360Df H335 H318		Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % Eye Dam. 1; H318: C ≥ 36 % Eye Irrit. 2; H319: 22 % ≤ C < 36 %	
	005-018-01-X	perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt, trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O ₂)), sodium salt, tetrahydrate; [3]	239-172-9 [1] 234-390-0 [2] 231-556-4 [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H360Df H332 H335 H318	GHS05 GHS08 GHS07 Dgr	H360Df H332 H335 H318		Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % Eye Dam. 1; H318: C ≥ 36 %	

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		sodium peroxoborate hexahydrate; [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]								Eye Irrit. 2; H319: 22 % ≤ C < 36 %	
Dossier submitter s proposal	Merge: 005-018-00-2 & 005-018-01-X	Retain: perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate Remove: [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	Modify: 239-172-9 [1] 234-390-0 [2]	Retain: 13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Modify: Repr.1B Acute Tox. 4	Modify: H360FD H332	Retain: GHS08 GHS07 Dgr	Modify: H360FD H332		Remove: Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % Add: Inhalation: ATE = 1.16 mg/L (dusts and mists)	
Resulting Annex VI entry if agreed by RAC and COM	TBD	perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2]	239-172-9 [1] 234-390-0 [2]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B Acute Tox. 4 STOT SE 3 Eye Dam. 1	H360FD H332 H335 H318	GHS05 GHS08 GHS07 Dgr	H360FD H332 H335 H318		Inhalation: ATE = 1.16 mg/L (dusts and mists) Eye Dam. 1; H318: C ≥ 36 %	#

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		perboric acid (HBO(O2)), sodium salt, tetrahydrate sodium peroxoborate hexahydrate [3]								Eye Irrit. 2; H319: 22 % ≤ C < 36 % §	
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