

SUBSTANCE SODIUM PERBORATE;

NAME: PERBORIC ACID, SODIUM

SALT

EC NUMBERS: 239-172-9

234-390-0

CAS NUMBERS: -

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF

SODIUM PERBORATE; PERBORIC ACID, SODIUM SALT

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CMR¹ PROPERTIES

Adopted on 30 May 2014

¹CMR means carcinogenic, mutagenic or toxic for reproduction

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Substance Name: Sodium perborate perboric acid, sodium salt

EC Numbers: 239-172-9

234-390-0

CAS numbers: -

• The substances are identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to their classification as toxic for reproduction category 1B², which corresponds to classification as toxic for reproduction category 2³.

Summary of how the substances meet the criteria set out in Article 57 of the REACH Regulation

Sodium perborate; perboric acid, sodium salt are covered by Index numbers 005-018-00-2, 005-018-01-X, 005-019-00-8, 005-019-01-5 of Regulation (EC) No $1272/2008^4$ in Annex VI, Part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) for reproductive toxicity, Rep. 1B (H360Df: "May damage the unborn child. Suspected of damaging fertility").

Therefore this classification of sodium perborate; perboric acid, sodium salt in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57(c) of REACH.

Registration dossiers submitted for the substance: Yes

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²Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances, OJ L 353, p.1, 31.12.2008

³Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC), OJ L 353, p.1, 31.12.2008.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Please note that any other possible hydrate of sodium perborate which is not explicitly mentioned in this Annex XV dossier is still, in principle, within the scope of the proposal.

Table 1: Substance identity

EC number:	239-172-9 234-390-0
EC name:	sodium perborate perboric acid, sodium salt
CAS number (in the EC inventory):	15120-21-5 11138-47-9
CAS numbers:	10332-33-9 ^e 13517-20-9 ^f 10486-00-7 ^g 37244-98-7 ^h 90568-23-3 ⁱ 125022-34-6 ^j
CAS names:	Perboric acid (HBO(O ₂)), sodium salt, monohydrate ^e Perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt, trihydrate ^f Perboric acid (HBO(O ₂)), sodium salt, hydrate (1:1:4) ^g . Perboric acid, sodium salt, tetrahydrate ^h Borate(2-), tetrahydroxybis[μ -(peroxy- κ O1: κ O2)]di-, sodium (1:2); molecular formula B2H4O8.2Na) ^h Borate(2-), tetrahydroxybis[μ -(peroxy- κ O1: κ O2)]di-, sodium, hydrate (1:2:6); molecular formula B2H4O8.6H ₂ O.2Na) ^j
Deleted CAS numbers:	
IUPAC name:	Sodium perborate

Index number in Annex VI of the CLP	005-018-00-2,					
Regulation	005-018-01-X,					
	005-019-00-8,					
	005-019-01-5					
Molecular formula:	BHO ₃ .Na ^b ; BH ₃ O ₄ .Na ^c ; BHO ₃ .H ₂ O.Na ^e ; BH ₃ O ₄ .3H ₂ O.Na ^f ; BHO ₃ .4H ₂ O.Na ^g					
Molecular weight range:	99.8 ^c					
	153.9 ⁹					
Synonyms:	PBS1					
	PBSM					
	Sodium perborate monohydrate					
	Sodium perborate tetrahydrate					
	PBS4					
	PBST					

Structural formula (from EU RAR 2007a):

c (monohydrate)

е

g (tetrahydrate)

Depending on the degree of hydration, several perboric acid, sodium salt compounds exist (EU RAR (2007a) on perboric acid, sodium salt; RPA (2008) report on borates; SCCS (2010b) opinion on sodium perborate and perboric acid).

Perboric acid, sodium salt is a white, odourless, water-soluble chemical compound with the chemical composition NaBO $_3$. It crystallises as the monohydrate NaBO $_3$ ·H $_2$ O, trihydrate NaBO $_3$ ·3H $_2$ O and tetrahydrate NaBO $_3$ ·4H $_2$ O. The monohydrate and the tetrahydrate are the commercially important forms. Different CAS numbers exist depending on the amount of water in the compound. The EC# 234-390-0 and CAS# 11138-47-9 are generic entries that have been presented as "collective" entries for the mono- and tetrahydrate of sodium perborate, even though they do not specifically describe such structures.

According to EU RAR (2007a) the peroxoboron anions have a dimeric structure, i.e. they exist either in anhydrous form or as hexahydrate.

This means that there may be in reality only 2 types of structures:

- The dimeric cyclic structure with 2 peroxy bridges:

This structure has historically been referred to as the "sodium perborate monohydrate" (empirical formula NaBO3.1H2O). These old name and formula do however not take into account the dimeric cyclic nature of the substance. The same structure may also have been wrongly represented by the empirical formula NaBO2.H2O2.

In reality, there would not be any crystalline water in "sodium perborate monohydrate". Hydrates of that dimeric structure also exist. For instance, what was historically known as "sodium perborate tetrahydrate" (empirical formula NaBO3.4H2O) is in fact the hexahydrate of the dimeric structure.

- The "dehydrated" form of sodium perborate. It is obtained from the "sodium perborate monohydrate" (which is not a true hydrate as explained above). The empirical formula is NaBO3. This structure is presented in the EU RAR (2007a) as not well-defined. It is supposed to consist of sodium borate and a boron oxygen radical.

However, it is still customary to use the "old" formulas and nomenclature of "sodium perborate monohydrate" and "sodium perborate tetrahydrate".

The perboric acid, sodium salt compounds listed above in Table 1, are all monosodium salts. Several other CAS numbers exist for e.g. disodium salt perborate compounds. These are, however, not described in this Annex XV dossier.

All perboric acids, sodium salt compounds, as listed in table 1, are available in different forms divided into the following two types of compounds. The classification differs slightly for the two types of compounds:

- 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

From all compounds listed in Table 1 only the perboric acid, sodium salt with the collective CAS number 11138-47-9 covering all mono- and tetrahydrates has been registered. However, this Annex XV dossier covers in addition also the remaining 7 CAS numbers, which all have the same harmonised classification as reproductive toxicant as the registered CAS number and a very similar structure. This is in line with the provisions of the Commission roadmap on

substances of very high concern⁵, which states that there might be cases in which non registered substances can still be considered relevant for identification. One example might be a substance that is currently not produced or used in Europe, but might be used as an alternative to another relevant SVHC. This exemption is particularly relevant when the most appropriate approach is the category approach (i.e., analogous substances).

Perboric acid, sodium salt and the mono- and tetrahydrates are in this dossier all referred to as "perboric acid, sodium salt (PBS)".

1.2 Composition of the substance

Mono-constituent

Purity: ≥80%

1.3 Physico-chemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57(c).

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⁵ http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%207664%202013%20INIT&r=http%3A%2F%2Fregister.consilium.europa.eu%2Fpd%2Fen%2F13%2Fst07%2Fst07664.en13.pdf

2 HARMONISED CLASSIFICATION AND LABELLING

Sodium perborate; perboric acid, sodium salt (all CAS numbers as indicated above) are subjected to harmonized classification with Repr 1B, H360Df with various specific concentration limits depending on the degree of hydration of the substance.

Sodium perborate; perboric acid, sodium salt are reactive oxidants and liberate hydrogen peroxide in aqueous solution under formation of sodium borate/ boric acid, which is considered to be the cause of the induction of the adverse effects on development and fertility.

The classification as Repr.1B and the specific concentration limits of PBS depend on the content of boron in the substances. This is similar to the classification of the borates and their hydrated forms, where the classification as Repr. 1B, H360Df and the specific concentration limits, depending on the boron content of the substances. The specific concentration limits are listed below.

Table 2: Classification according to part 3 of Annex VI, Table 3.1 of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS N	lo	Classification	Labelling		Concentration Limits	Notes
005-018-00-2	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; [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]	37244-98-7 [2]		Repr. Cat. 3; R62		41-62 47	Repr. Cat. 2; R61: C ≥ 10 % Repr. Cat. 3; R62: C ≥ 14 % Xi; R41: C ≥ 36 % Xi; R36: 22 % ≤ C < 36 %	
005-018-01-X	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; [3] [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] 231556-4 [3]	13517-20-9 37244-98-7 10486-00-7	2] Rep 3] Xn;	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xn; R20 Xi; R37-41		37-41-62 47	Repr. Cat. 2; R61: C≥ 10 % Repr. Cat. 3; R62: C≥ 14 % Xi; R41: C≥ 36 % Xi; R36: 22 % ≤ C < 36 %	E
005-019-00-8	perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; [3] sodium peroxoborate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	234-390-0 [1] 234-390-0 [2] 231-556-4 [3]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3]	Oxid. Sol. 3 Repr. 1B Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H302 H335 H318	GHS03 GHS05 GHS08 GHS07 Dgr	H272 H360Df H302 H335 H318	C ≥ 9 % Repr. 1B 6,5 % ≤ 0 Eye Dam C ≥ 22 %	. 1; H318: 5 2; H319:
005-019-01-5	perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; [3] sodium peroxoborate; [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below \$50 µm]	234-390-0 [1] 234-390-0 [2] 231-556-4 [3]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3]	Oxid. Sol. 3 Repr. 1B Acute Tox. 3 * Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360Df H331 H302 H335 H318	C ≥ 9 % Repr. 1B 6,5 % ≤ 0 Eye Dam C ≥ 22 %	. 1; H318: 2; H319:

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57(c).

4 HUMAN HEALTH HAZARD ASSESSMENT

With respect to CMR effects sodium perborate; perboric acid, sodium salt (all CAS numbers as indicated above) are subject to harmonized classification with Repr 1B, H360Df with various specific concentration limits depending on the degree of hydration of the substance).

Sodium perborate; perboric acid, sodium salt are reactive oxidants and liberate hydrogen peroxide in aqueous solution under formation of sodium borate/ boric acid which is considered to be the cause of the induction of the adverse effects on development and fertility.

The classification as Repr 1B and the specific concentration limits of sodium perborate; perboric acid, sodium salt depend on the content of boron in the substances. This is similar to the classification of the borates and their hydrated forms, where the classification as Repr 1B, H360Df and the specific concentration limits, depend on the boron content of the substances (see chapter 2).

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(c).

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57(c).

6.2 CMR assessment

Sodium perborate; perboric acid, sodium salt are covered by Index numbers 005-018-00-2, 005-018-01-X, 005-019-00-8, 005-019-01-5 of Regulation (EC) No $1272/2008^6$ in Annex VI, Part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) for reproductive toxicity, Rep. 1B (H360Df: "May damage the unborn child. Suspected of damaging fertility").

Therefore this classification of Sodium perborate; perboric acid, sodium salt in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57(c) of REACH.

6.3 Substances of equivalent level of concern assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57(c).

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

7 REFERENCES

- CLP Regulation 1272/2008. "Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006".
- ECHA C&L inventory database, 2013: http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database
- EU RAR (2007a). European Risk Assessment Report on perboric acid, sodium salt (CAS 11138-47-9). European Chemicals Bureau.