

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Following the new classification of sodium perborate and perboric acid as toxic to reproduction according to the Commission Regulation 790/2009¹ a scientific evaluation is needed for their continued use

1. Background

Sodium perborate and perboric acid

The Cosmetics Directive as modified by the Council and the European Parliament (2003/15/EC²), which is based on an opinion of the SCCNFP of September 2001 (SCCNFP/0474/01, final), stipulates that “*the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.*”

On 21 August 2008 and on 15 January 2009 the Commission adopted respectively Directives 2008/58/EC³ and 2009/2/EC⁴ amending Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances providing new classifications for some boron compounds⁵. On this occasion sodium perborate and perboric acid have been classified as toxic to reproduction in category 2 and 3 with specific concentration limits. These specific concentration limits indicate that a threshold for reproductive toxicity could be established.

Sodium perborate and perboric acid are covered by the following CAS nos 15120-21-5; 11138-47-9; 12040-75-1; 7632-04-4; 10332-33-9; 13517-20-9; 37244-98-7 and 10486-00-7 (see the annex I).

¹ OJ L 235, 5.9.2009, p. 1. Commission Regulation 790/2009, amending for technical purposes the EC Regulation 1272/2008 which deleted Annex I of Council Directive 67/548/EEC as from 20 January 2009 (Article 55(11)), took over the classification provided by the Directives 2008/58/EC and 2009/2/EC, implementing the 30 and 31 ATP, respectively, to the Directive 67/548/EEC

² OJ L 66, 11.03.2003, p. 26. See recital (12).
(12) “*The SCCNFP stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(2) as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.*”
(2) OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission. Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

³ OJ L 246, 15.09.2008, p. 1.

⁴ OJ L 11, 16.01.2009, p. 6

⁵ As indicated above, the classification provided by these two Directives has been taken over by Commission Regulation 790/2009 amending EC Regulation 1272/2008.

Sodium perborate and perboric acid might be covered by the restrictions laid down in Annex III entries 1a and 1b of the Cosmetics Directive 76/768/EEC "Boric acid, borates and tetraborates" (this question is addressed in the mandate on some boron compounds with a new classification as mutagenic and/or toxic to reproduction issued in parallel). Sodium perborate and perboric acid might also be covered by entry 12 of Annex III of the Cosmetic Directive, "Hydrogen peroxide, and other compound or mixtures that release hydrogen peroxide..." (attached Annex II).

An applicant has applied for the continued use of sodium perborate in powdered, oxidative hair dye formulations up to a maximum concentration applied to the hair of 3.0% (calculated as boric acid).

In light of the new classification of sodium perborate and perboric acid a safety evaluation by the SCCS is necessary, taking into account the scientific data on which the classification has been based and the data provided by the applicant for sodium perborate.

In addition to any answers provided to questions 1 and 2 in the mandate on some boron compounds with a new classification as mutagenic and/or toxic to reproduction issued in parallel, the SCCS is asked to address the following questions:

- (1) *Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?*
- (2) *If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate?*
- (3) *Furthermore, does the SCCS consider with the provided scientific data that sodium perborate is safe, when used in (powdered), oxidative hair dye formulations up to a maximum concentration on the head of max.3.0% calculated as boric acid corresponding to a release of x volumen percentage hydrogen peroxide?*
- (4) *Sodium perborate and perboric acid have different classifications depending on the percentage content of particles with an aerodynamic diameter below 50 µm. Does the SCCS consider that this has an impact on their safe use in cosmetic products?*

Annex I: List of boron compounds newly classified as CMR 2 (Commission Regulation 790/2009) and not yet covered by the Annex II of the Cosmetics Directive (76/768/EEC)

Chemical name	EC No	CAS No	Classification	Concentration Limits of Regulation 790/2009
sodium perborate; [1] perboric acid, sodium salt; [2] perboric acid, sodium salt, monohydrate; [3] sodium peroxometaborate; [4] perboric acid (HBO(O ₂)), sodium salt, monohydrate; [5] sodium peroxoborate; [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] - [3] 231-556-4 [4] - [5]	15120-21-5 [1] 11138-47-9 [2] 12040-72-1 [3] 7632-04-4 [4] 10332-33-9 [5]	O; R8 Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xn; R22 Xi; R37-41	C ≥ 25 %: T; R61-22-37-41-62 22 % ≤ C < 25 %: T; R61-37-41-62 20 % ≤ C < 22 %: T; R61-36/37-62 14 % ≤ C < 20 %: T; R61-36-62 9 % ≤ C < 14 %: T; R61-62 6,5 % ≤ C < 9 %: T; R61
sodium perborate; [1] perboric acid, sodium salt; [2] perboric acid, sodium salt, monohydrate; [3] sodium peroxometaborate; [4] perboric acid (HBO(O ₂)), sodium salt, monohydrate; [5] sodium peroxoborate; [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] - [3] 231-556-4 [4] - [5]	15120-21-5 [1] 11138-47-9 [2] 12040-72-1 [3] 7632-04-4 [4] 10332-33-9 [5]	O; R8 Repr. Cat. 2; R61 Repr. Cat. 3; R62 T; R23 Xn; R22 Xi; R37-41	C ≥ 25 %: T; R61-22-23-37-41-62 22 % ≤ C < 25 %: T; R61-20-37-41-62 20 % ≤ C < 22 %: T; R61-20-36/37-62 14 % ≤ C < 20 %: T; R61-20-36-62 9 % ≤ C < 14 %: T; R61-20-62 6,5 % ≤ C < 9 %: T; R61-20 3 % ≤ C < 6,5 %: Xn; R20
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	- [1] - [2] - [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xi; R37-41	C ≥ 36 %: T; R61-37-41-62 22 % ≤ C < 36 %: T; R61-36/37-62 20 % ≤ C < 22 %: T; R61-37-62 14 % ≤ C < 20 %: T; R61-62 10 % ≤ C < 14 %: T; R61

Chemical name	EC No	CAS No	Classification	Concentration Limits of Regulation 790/2009
particles with an aerodynamic diameter of below 50 µm]				
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]	- [1] - [2] - [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xn; R20 Xi; R37-41	C ≥ 36 %: T; R61-20-37-41-62 25 % ≤ C < 36 %: T; R61-20-36/37-62 22 % ≤ C < 25 %: T; R61-36/37-62 20 % ≤ C < 22 %: T; R61-37-62 14 % ≤ C < 20 %: T; R61-62 10 % ≤ C < 14 %: T; R61

Entry 12 of Annex III of the Cosmetics Directive - Annex III (Part 1)

List of substances which cosmetic products must not contain except subject to the restriction and conditions laid down

12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% of H ₂ O ₂ (40 volumes), present or released (b) 4% of H ₂ O ₂ , present or released (c) 2% of H ₂ O ₂ , present or released (d) 0.1% of H ₂ O ₂ , present or released	(a) Wear suitable gloves (a) (b) (c) Contains hydrogen peroxide Avoid contact with eyes Rinse immediately if product comes into contact with them
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