

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Updated, revised request for a scientific opinion following the new classification of some boron compounds as mutagenic and/or toxic to reproduction according to the Commission Regulation 790/2009¹

1. Background

Boron Compounds

In its opinion of 23 September 1998 on “boric acid, borates and tetraborates” (SCCNFP/0025/98), the SCCNFP established limits for the safe use of some boron compounds. This opinion has been implemented into entries 1a and 1b of Annex III, part 1 of the Cosmetics Directive (76/768/EEC as amended). The detailed entries are included in the annex I to this mandate.

On 21 August 2008 and on 15 of January 2009 the Commission adopted respectively Directives 2008/58/EC² and 2009/2/EC³ 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 compounds⁴. The Annex II attached to this mandate lists the substances concerned by this request. In most instances, the classification of the boron compounds is toxic for reproduction, category 2 (CMR Repr. cat. 2), with varying specific concentration limits. These specific concentration limits set for the boron compounds indicate that thresholds for the reproductive toxicity could be established.

The Cosmetics Directive as modified by the Council and the European Parliament (2003/15/EC⁵), 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*

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 246, 15.09.2008, p. 1.

³ OJ L 11, 16.01.2009, p. 6

⁴ As indicated above, the classification provided by these two Directives has been taken over by Commission Regulation 790/2009 amending EC Regulation 1272/2008.

⁵ 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).

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.”

In light of the new classification of some boron compounds a safety evaluation by the SCCS is necessary, taking into account the scientific data on which the classification has been based.

Octaborates

Disodium octaborate tetrahydrate was mentioned as one of the test substances for the 1998 SCCNFP opinion on borates. However, the octaborates are not specifically named in the rather generic entry 1a and 1b of Annex III of the Cosmetics Directive, neither are they listed in the inventory or CosIng. So for reasons of clarity, there is a need to know whether they are covered by entry 1a and/or 1b of Annex III of the Cosmetics Directive 76/768/EEC.

Perborates

For perborates, see also the separate mandate for these substances issued in parallel.

2. Terms of Reference

Boron compounds

- (1) *Based on the current knowledge on the chemistry, biology and toxicology of boron can the SCCS inform the Commission which of the substances listed in the annex II, newly classified substances to this mandate, are covered by the entries 1a and 1b of Annex III, of the Cosmetics Directive 76/768/EEC?*
- (2) *Based on the answer to question 1, and taking into account the scientific data used in the classification of these substances, the SCCS is asked if:*
 - (a) *the substances that are covered by the entries 1a and 1b of Annex III and which are currently restricted by Directive 76/768/EEC at a maximum use concentration above the specific concentration limits for classification set out in the Commission Regulation 790/2009 are safe when used in cosmetic products at the specific concentration limits set out in the Commission Regulation 790/2009?*
 - (b) *the substances that are not covered by the entries 1a and 1b of Annex III can safely be used in cosmetic products at concentrations levels below or equal to the specific concentrations limits laid down the Commission Regulation 790/2009?*

Octaborates

3. (a) *Based on the current scientific knowledge on the chemistry, biology and toxicology of boron and its compound does the SCCS consider that octaborates are covered by Annex III of the Cosmetics Directive, entry 1a and 1b? and if covered, considering that octaborates are not classified, should the current restrictions limits of Annex III entry 1a and 1b be applied for the octaborates*

(b) *if not covered, does the SCCS have any scientific concern about the safe use of octaborates in cosmetic products?*

Annex I

Entries 1a and 1b of Annex III (Part 1) of the Cosmetics Directive

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

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|---|--|---|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 1a | Boric acid, borates and tetraborates with the exception of substance no 1184 in Annex II | (a) Talc (b) Products for oral hygiene (c) Other products (excluding bath products and hair waving products) | (a) 5% (by mass/mass as boric acid) (b) 0.1% (by mass/mass as boric acid) (c) 3% (by mass/mass as boric acid) | (a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid) (b) 1. Not to be used in products for children under 3 years of age (c) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass | (a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin (b) 1. Not to be swallowed 2. Not to be used in products for children under 3 years of age (c) 1. Not to be used in products for children under 3 years of age 2. Not to |

| | | | | | |
|----|--------------|---|---|--|---|
| | | | | as boric acid) | be used on peeling or irritated skin |
| 1b | Tetraborates | (a) Bath products (b) Hair waving products | (a) 18% (by mass/mass as boric acid) (b) 8% (by mass/mass as boric acid) | (a) Not to be used in products for children under 3 years of age | (a) Not to be used of bathing children under 3 years of age (b) Rinse well |

Annex II: 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 |
|--|---|---|---|--|
| boric acid; [1] boric acid, crude natural, containing not more than 85 per cent of H ₃ BO ₃ calculated on the dry weight [2] | 233-139-2 [1] 234-343-4 [2] | 10043-35-3 [1] 11113-50-1 [2] | Repr. Cat. 2; R60-61 | C ≥ 5,5 %: T; R60-61 |
| diboron trioxide; boric oxide | 215-125-8 | 1303-86-2 | Repr. Cat. 2; R60-61 | C ≥ 3,1 %: T; R60-61 |
| disodium tetraborate, anhydrous; boric acid, disodium salt; [1] tetraboron disodium heptaoxide, hydrate; [2] orthoboric acid, sodium salt [3] | 215-540-4 [1] 235-541-3 [2] 237-560-2 [3] | 1330-43-4 [1] 12267-73-1 [2] 13840-56-7 [3] | Repr. Cat. 2; R60-61 | C ≥ 4,5 %: T; R60-61 |
| disodium tetraborate decahydrate; borax decahydrate | 215-540-4 | 1303-96-4 | Repr. Cat. 2; R60-61 | C ≥ 8,5 %: T; R60-61 |
| disodium tetraborate pentahydrate; borax pentahydrate | 215-540-4 | 12179-04-3 | Repr. Cat. 2; R60-61 | C ≥ 6,5 %: T; R60-61 |
| dibutyltin hydrogen borate | 401-040-5 | 75113-37-0 | Muta. Cat. 3; R68 Repr. Cat. 2; R60-61 T; R48/25 Xn; R21/22 Xi; R41 R43 N; R50-53 | |
| sodium perborate; [1] perboric acid, sodium salt; [2] perboric acid, sodium salt, monohydrate; [3] sodium peroxometaborate; [4] perboric acid (HBO(O ₂)), sodium | 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 |

| Chemical name | EC No | CAS No | Classification | Concentration Limits of Regulation 790/2009 |
|--|---|---|--|---|
| salt, monohydrate; [5] sodium peroxoborate; [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] | | | | |
| 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 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 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 |
| perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt, trihydrate; [1] perboric acid, sodium salt, | - [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 |

| Chemical name | EC No | CAS No | Classification | Concentration Limits of Regulation 790/2009 |
|---|-------|--------|----------------|---|
| 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] | | | | 20 % ≤ C < 22 %: T; R61-37-62 14 % ≤ C < 20 %: T; R61-62 10 % ≤ C < 14 %: T; R61 |