



Scientific Committee on Consumer Safety

SCCS

OPINION ON

the safety of boron compounds in cosmetic products

The SCCS adopted this opinion at its 4th plenary meeting

of 12 December 2013

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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ISSN 1831-4767

ISBN 978-92-79-30124-7

Doi: 10.2772/7521

ND-AQ-13-017-EN-N

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http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

ACKNOWLEDGMENTS

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Keywords: SCCS, scientific opinion, cosmetic ingredients, boron compounds, Regulation 1223/2009

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of boron compounds in cosmetic products, 12 December 2013, SCCS/1523/13

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1. BACKGROUND

Article 15, paragraph 2, of Regulation (EC) No 1223/2009, provides that the use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. This prohibition for use in cosmetic products applies as from the date of application of the classification as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, unless an authorisation measure is adopted within 15 months of the inclusion of the substances concerned in that Regulation. This authorisation measure is adopted by the Commission, by way of exception, where all the conditions lay down for this purpose in Article 15, paragraph 2, of Regulation (EC) No 1223/2009 are fulfilled.

Several boron compounds have been classified as CMR 1B substances under Part 3 of Annex VI to Regulation (EC) No 1272/2008. They are already covered by entries 1a, 1b, respectively 12 in Annex III to Regulation (EC) No 1223/2009. In the case of these substances, the conditions for exception to the prohibition rule laid down in Article 15, paragraph 2, of Regulation (EC) No 1223/2009 have not been fulfilled.

It is therefore necessary to amend entries 1a, 1b and 12 of Annex III to the Cosmetics Regulation in order to indicate that those boron compounds, sodium perborate and perboric acid which have been classified as CMR 1B are not allowed anymore for use in cosmetic products.

However a clarification is needed on some scientific aspect regarding the whole group of borates. It appears that borates, on contact with water, tetraborates and octaborates form boric acid, which is classified as CMR 1B substance. If there is scientific evidence on this process, the whole group of borates, tetraborates and octaborates could then be prohibited for use in cosmetic products.

Therefore, we would like to ask for a clarification on this aspect for the borates, tetraborates and octaborates reported in Cosing database such as: MEA-BORATE; MIPA-BORATE; POTASSIUM BORATE; TRIOCTYLDODECYL BORATE; ZINC BORATE.

For your information several scientific opinions have already been adopted on boron compounds:

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers adopted its opinion concerning Boric Acid, Borates and Tetraborates on 23 September 1998 (SCCNFP/0025/98)

The Scientific Committee on Consumer Safety adopted its scientific opinions on Sodium perborate and perboric acid (SCCS/1345/10) and on Boron compound (SCCS/1249/09) on the 22 June 2010.

2. TERMS OF REFERENCE

In the light of the classification of the Boric acid as CMR 1B substances under Part 3 of Annex VI to Regulation (EC) No 1272/2008, the SCCS is asked to address the following questions:

1. Based on the current knowledge on the chemistry of borates, tetraborates and octaborates, does the SCCS consider that these compounds break in the product, due to contact with water, into boric acid?

2. If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to boric acid should apply to the whole group of borates?

3. CLARIFICATION

Effect of water on selected boron compounds

Borate is the accepted common name for the metal salts of boric acid which comprise the following family of chemicals: i.a. potassium borate, zinc borate, sodium tetraborate decahydrate, sodium tetraborate pentahydrate, sodium tetraborate (anhydrous borax), disodium octaborate (anhydrous), disodium octaborate tetrahydrate, and sodium metaborate.

MEA-borate is an abbreviation for monoethanolamine borate. The systemic name is: 2-aminoethanol, monoester with boric acid. As an ester of borate it is expected to hydrolyse to boric acid and ethanolamine in contact with water. No information is however, available on the rate of hydrolysis.

MIPA-borate or boric acid (H_3BO_3), compd. with 1-amino-2-propanol (1:1) is a mixture between boric acid and 1-amino-2-propanol also called isopropanolamine borate. Thus, boric acid is present when dissolved in water.

Trioctyldodecyl borate is the triester of boric acid and 2-octyldodecan-1-ol. It is a liquid and is easily hydrolysed to boric acid and 2-octyldodecan-1-ol in the presence of water.

Boric acid is a weak acid with a pKa of 9.2 and exists primarily as the undissociated acid (H_3BO_3) in aqueous solution at physiological pH, as do the borate salts. All the substances mentioned above are expected to have chemical, biological and toxicological properties similar to boric acid as these compounds form boric acid in contact with water. However, only limited studies are available on MEA-borate, MIPA-borate, and trioctyldodecyl borate.

In Annex 1 some information is provided concerning boron compounds reported in the Background and listed in CosIng database.

4. CONCLUSION

1. *Based on the current knowledge on the chemistry of borates, tetraborates and octaborates, does the SCCS consider that these compounds break in the product, due to contact with water, into boric acid?*

The SCCS is of the opinion that all the substances mentioned above (borates, tetraborates and octaborates) as well as other boric acid salts/esters reported in CosIng database such as MEA-borate, MIPA-borate, potassium borate, trioctyldodecyl borate and zinc borate, break in the product due to contact with water into boric acid.

2. *If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to boric acid should apply to the whole group of borates?*

SCCS considers that these compounds have chemical, biological and toxicological properties similar to boric acid. Therefore the general restrictions applicable to boric acid should apply to the whole group of borates.

5. MINORITY OPINION

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6. REFERENCES

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Annex 1.

Below is the EC No, CAS No and functions of the substances mentioned in the Background and Terms of reference.

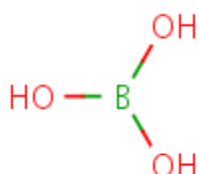
Boric acid

EC No. 233-139-2 / 234-343-4

CAS No. 10043-35-3 / 11113-50-1

Mol.weight: 61.83, Mol.formula: H_3BO_3

Function: Antimicrobial, buffering, denaturant



Sodium tetraborate (anhydrous borax), Disodium tetraborate, anhydrous (boric acid, disodium salt);

EC No. 215-540-4 (both)

CAS No. 1330-43-4 / 1303-96-4

Mol.weight: 201.22, Mol.formula: $B_4O_7 \cdot 2Na$

Function: Buffering



Disodium octaborate tetrahydrate is a solid solution¹ of boric acid and disodium tetraborate decahydrate.

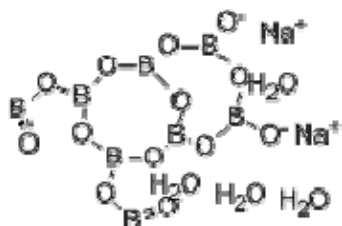
Boron sodium oxide, tetrahydrate

CAS No 12280-03-4

Mol.weight: 412.53, Mol.formula: $Na_2B_8O_{13} \cdot 4H_2O$

Function: No information

¹ A **solid solution** is a solid-state solution of one or more solutes in a solvent. Such a mixture is considered a solution rather than a compound when the crystal structure of the solvent remains unchanged by addition of the solutes, and when the mixture remains in a single homogeneous phase. IUCLID: Disodium octaborate tetrahydrate is not a true compound but a solid solution of borax in boric acid.



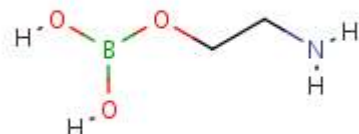
MEA-Borate, 2-Aminoethanol, monoester with boric acid.

EC No. 233-829-3

CAS No: 10377-81-8

Mol.weight: 104.90, Mol.formula: $C_2H_8NBO_3$

Function: Buffering



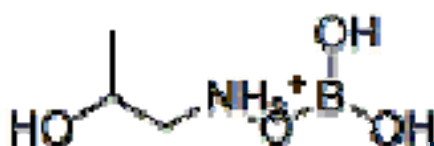
MIPA-borate (2-hydroxypropyl)ammonium dihydrogen orthoborate), Isopropanolamine borate

EC No. 268-109-8

CAS No. 68003-13-4

Mol.weight: 136.94, Mol.formula: $C_3H_9NO \cdot H_3BO_3$

Function: Viscosity controlling

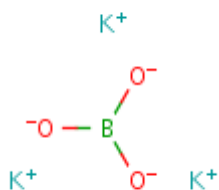


Potassium borate, boric acid, potassium salt

CAS No. 12712-38-8

Mol.weight: 176.10, Mol.formula: K_3BO_3

Function: Buffering

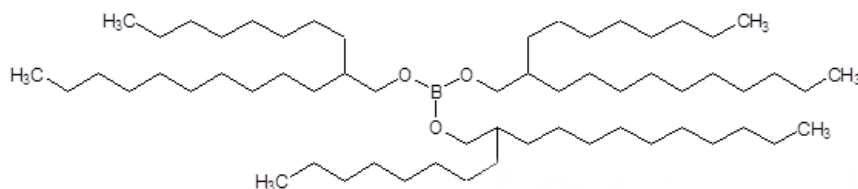


Trioctyldodecyl borate, is the triester of boric acid and 2-octyldodecan-1-ol

No CAS No. and EC No. available

Mol.weight: 903.43, Mol.formula: $C_{60}H_{123}BO_3$

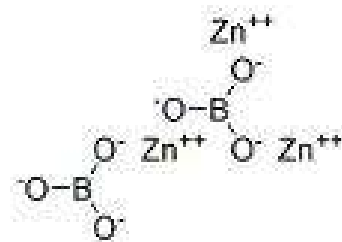
Function: Emollient



Zinc borate

Mol.weight², Mol.formula: $B_2O_6Zn_3 \cdot xH_2O$

Function: Antimicrobial



² Various variants of Zinc borate (hydrate) are available.