



Commentary

Opinion of the scientific committee on consumer safety (SCCS) – 2nd Revision of the safety of the use of poly(hexamethylene) biguanide hydrochloride or polyaminopropyl biguanide (PHMB) in cosmetic products



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ABSTRACT

Conclusion of the opinion: On the basis of the data available, the SCCS concludes that Polyaminopropyl Biguanide (PHMB) is not safe for consumers when used as a preservative in cosmetic spray formulations and in all cosmetic products up to the maximum concentration of 0.3%. The safe use could be based on a lower use concentration and/or restrictions with regard to cosmetic products' categories. Dermal absorption studies on additional representative cosmetic formulations are needed.

PHMB is used in a variety of applications other than cosmetics. General exposure data from sources others than cosmetics should be submitted for the assessment of the aggregate exposure of PHMB.

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Poly(hexamethylene) biguanide hydrochloride (PHMB) (CAS Nos. 32289-58-0 or 27083-27-8, INCI Polyaminopropyl Biguanide), is authorised as preservative in cosmetic products at a maximum permitted concentration of 0.3%, according to Annex V of the Regulation (EC) No. 1223/2009.

Polyaminopropyl Biguanide (PHMB) is classified as CMR2 according to the Commission Regulation (EU) No. 944/2013 of 2 October 2013 amending for the purposes of its adaptation to technical and scientific progress the Regulation (EC) No. 1272/2008. In particular, in recital 7 of Commission Regulation (EU) No. 944/2013 it is reported that for PHMB the specific hazard 'acute toxicity (inhalation)' is under evaluation by the RAC. The classification will apply from 1st January 2015. As a consequence, PHMB would be prohibited from 1st January 2015 as cosmetic ingredient according to art. 15 (1) of Regulation (EC) No. 1223/2009 on cosmetic products.

However, article 15 (1) of Regulation (EC) No. 1223/2009 states

that 'a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation'.

In January 2014, the Commission received a submission from Cosmetics Europe4 on PHMB, intended to demonstrate the safety of the ingredient when used as a preservative in cosmetics products up to a maximum concentration of 0.3%.

After the commenting period, which followed the publication of SCCS/1535/14 on 18 June 2014, a report on an *in vitro* mammalian cell gene mutation test and a draft of a new *in vitro* percutaneous absorption study were provided by the applicant along with submission dossier II and further references. These documents were used for revising the opinion.

On the basis of the data available, the SCCS concludes that Polyaminopropyl Biguanide (PHMB) is not safe for consumers when used as a preservative in all cosmetic products and in cosmetic spray formulations up to the maximum concentration of 0.3%.

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The safe use could be based on a lower use concentration and/or restrictions with regard to cosmetic products' categories. Dermal absorption studies on additional representative cosmetic formulations are needed.

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General exposure data from sources others than cosmetics should be submitted for the assessment of the aggregate exposure of PHMB.

Transparency document

Transparency document related to this article can be found online at <http://dx.doi.org/10.1016/j.yrtph.2015.09.035>.

Reference

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_157.pdf.