



## Commentary

## Opinion of the scientific committee on consumer safety (SCCS) – Final opinion on Polyaminopropyl Biguanide (PHMB) in cosmetic products - Submission III



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EC: 608-723-9 and 608-042-7

Poly(hexamethylene) biguanide hydrochloride (PHMB) (CAS 32289-58-0/27083-27-8/28757-47-3/133029-32-0) with INCI name Polyaminopropyl Biguanide, is currently listed in Annex V (entry 28) of the Regulation (EC) No. 1223/2009 (Cosmetics Regulation) as preservative to be used in all cosmetic products up to a maximum concentration of 0.3%.

Polyaminopropyl Biguanide (PHMB) is classified as CMR 2 (Carc. 2) according to the Commission Regulation (EU) No. 944/20132 of 2 October 2013 amending for the purposes of its adaptation to technical and scientific progress the Regulation (EC) No. 1272/20083. The classification applies from 1st January 2015 and according to Art. 15 (1) of the Cosmetics Regulation, PHMB is considered prohibited as cosmetic ingredient from 1st January 2015.

However, Art. 15 (1) of the Cosmetics Regulation 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'.

The SCCS published an opinion on the safety of PHMB in June 2014 successively revised in July 2015 (SCCS/1535/14)<sup>4</sup> in which they concluded that:

"Polyaminopropyl Biguanide (PHMB) is not safe for consumers when used as a preservative 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.

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

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."

In May 2016, Cosmetics Europe transmitted a new safety dossier on PHMB that addresses the major issues raised by the SCCS notably i) a lower maximum concentration of 0.1%, ii) new dermal absorption studies on representative formulations and iii) aggregate exposure data.

In light of the data provided by the applicant in Submission III, the SCCS is of the opinion that the use of Polyaminopropyl Biguanide (PHMB) as a preservative in all cosmetic products up to 0.1% is safe.

As no new safety data on inhalation is available on PHMB, its use in sprayable formulations is not advised.

### Opinion to be cited as

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### Transparency document

Transparency document related to this article can be found online at <http://dx.doi.org/10.1016/j.yrtph.2017.04.013>.

### Reference

[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_204.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_204.pdf).