

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

### Request for a scientific opinion: Polyaminopropyl Biguanide (PHMB)

CAS Nos. 32289-58-0 or 27083-27-8 - Submission I

#### 1. Background

Poly(hexamethylene) biguanide hydrochloride (PHMB) (CAS Nos. 32289-58-0 or 27083-27-8, INCI Polyaminopropyl Biguanide), is authorized as preservative in cosmetic products at a maximum permitted concentration of 0.3%, according to Annex V of the Regulation (EC) No. 1223/2009<sup>1</sup>.

Polyaminopropyl Biguanide (PHMB) is classified as CMR2 according to the Commission Regulation (EU) No. 944/2013<sup>2</sup> of 2 October 2013 amending for the purposes of its adaptation to technical and scientific progress the Regulation (EC) No. 1272/2008<sup>3</sup>. 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 1<sup>st</sup> January 2015. As a consequence, PHMB would be prohibited from 1<sup>st</sup> 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 Europe<sup>4</sup> 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%.

#### 2. Terms of reference

1. *In view of the above, and taking into account the scientific data provided, SCCS is requested to give its opinion on the safety of Polyaminopropyl Biguanide (PHMB) when used as a preservative in cosmetics products up to a maximum concentration of 0.3%.*
2. *SCCS is requested to address any further scientific concerns on the ingredient Polyaminopropyl Biguanide (PHMB) in particular regarding its use in spray formulation.*

**Deadline: July 2014**

1- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

2- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF>

3- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>

4--Cosmetics Europe- European Cosmetics Toiletry and Perfumery Association

**Annex:**

1. Dossier on the safety of Polyaminopropyl Biguanide (PHMB) submitted by Cosmetics Europe in January 2014