



Brussels, **XXX**  
[...] (2019) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of  
the Council on cosmetic products**

(Text with EEA relevance)

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## **amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products<sup>1</sup>, and in particular Article 31(2) thereof,

Whereas:

- (1) The substance 4-(3-ethoxy-4-hydroxyphenyl)butan-2-one (CAS Number 569646-79-3), which has been assigned the name Hydroxyethoxyphenyl Butanone (HEPB) under the International Nomenclature of Cosmetic Ingredients, is used as a cosmetic preservative and as a skin conditioning agent. It is currently not listed in Regulation (EC) No 1223/2009.
- (2) The Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 7 April 2017<sup>2</sup> that, under an aggregate exposure scenario, HEPB can be considered safe when used as a preservative in rinse off, oral care and leave-on cosmetic products at a maximum concentration of 0,7 %. The SCCS also concluded that more evidence would be needed to exclude eye irritation.
- (3) Following concerns raised by several Member States on HEPB as a potential eye irritant and additional scientific data submitted by the applicant, the SCCS concluded in its opinion of 5 March 2019<sup>3</sup> that, under an aggregate exposure scenario, the use of HEPB as a preservative in rinse-off, oral care and leave-on cosmetic products at a maximum concentration of 0,7 % is safe with regard to eye irritation.
- (4) In light of the opinions mentioned above and in order to take into account technical and scientific progress, HEPB should be allowed for use as a preservative in rinse off, oral care and leave-on cosmetic products at a maximum concentration of 0,7 % in ready for use preparation.
- (5) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Ethylzingerone - 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98, SCCS/1582/16, 7 April 2017

<sup>3</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Ethylzingerone - 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98 – Submission II eye irritation, preliminary version of 21 December 2018, final version of 5 March 2019, SCCS/1604/18

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex V to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*