



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)

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

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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 products¹, 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 2017² 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 2019³ 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,

¹ OJ L 342, 22.12.2009, p. 59.

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

³ 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



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ANNEX

ANNEX

to

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ANNEX

In Annex V to Regulation (EC) No 1223/2009, the following entry is added:

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'60	4-(3-ethoxy-4-hydroxyphenyl)butan-2-one	Hydroxyethoxyphenyl Butanone	569646-79-3	933-435-8	Rinse-off products Oral products Leave-on products	0,7 %'		