Commission Regulation (EU) 2019/1858 of 6 November 2019 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) 2019/1858

of 6 November 2019

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[(1)], 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, has the function of preservative and skin conditioning. 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[(2)] 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 to it by the applicant, the SCCS concluded in its opinion of 5 March 2019[(3)] 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,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/1858. (See end of Document for details)*

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, 6 November 2019.

For the Commission

The President

Jean-Claude JUNCKER