Commission Regulation (EU) 2016/1121 of 11 July 2016 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) 2016/1121

of 11 July 2016

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 Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride, which has been assigned the name Ethyl Lauroyl Arginate HCl under the International Nomenclature of Cosmetic Ingredients (INCI), is currently regulated in entry 197 of Annex III and in entry 58 of Annex V to Regulation (EC) No 1223/2009. Under entry 58 of Annex V, Ethyl Lauroyl Arginate HCl is allowed as a preservative in cosmetic products, except lip products, oral products and spray products, at a maximum concentration of 0,4 % w/w.

(2) The Scientific Committee on Consumer Safety (SCCS) adopted a scientific opinion on the safety of Ethyl Lauroyl Arginate HCl in oral products on 19 September 2013 (revised on 12 December 2013)[(2)] and an addendum to that opinion on 16 December 2014 (revised on 25 March 2015)[(3)].

(3) The SCCS concluded that Ethyl Lauroyl Arginate HCl is safe for use as a preservative in mouthwashes at a maximum concentration of 0,15 % w/w, but not in oral products in general. The SCCS also considered that the exposure estimations suggested that the acceptable daily intake for children aged 3 to 9 may be exceeded, when adding food exposure and cosmetic exposure. The SCCS thus concluded that the continuous use of Ethyl Lauroyl Arginate HCl as a preservative in mouthwashes at that concentration for children is not safe.

(4) In light of that SCCS opinion, the Commission considers that Ethyl Lauroyl Arginate HCl should be allowed for use as a preservative up to a concentration of 0,15 % w/w in mouthwashes, expect for children under the age of 10.

(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,

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1121. (See end of Document for details)*

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, 11 July 2016.

For the Commission

The President

Jean-Claude JUNCKER