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Delegations will find attached document D041688/01.

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EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) 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)

D041688/01

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)

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 15 (1) thereof,

Whereas:

(1) Article 15 (1) of Regulation (EC) No 1223/2009 prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2], unless these substances have been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products.

(2) The substance Methenamine 3-chloroallylochloride, with the International Nomenclature of Cosmetic Ingredients (INCI) name Quaternium-15, is currently authorised as a preservative in entry 31 of Annex V to Regulation 1223/2009 at a use concentration of up to 0,2 % w/w in a ready for use preparation.

(3) Quaternium-15 is a mixture of isomers, where the cis form is the dominant isomer component and the trans form is the minor one present as an impurity. The cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) has been classified as a substance toxic for reproduction of category 2 under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures as amended by Commission Regulation (EC) No 790/2009[3]. Pursuant to Article 2 of Regulation (EC) No 790/2009 this classification started to apply on 1 December 2010, the date on which Article 15 (1) of Regulation (EC) No 1223/2009 started to apply as well. The use of this substance in cosmetic products was therefore automatically banned as of that date.

1 OJ L 342, 22.12.2009, p. 59.
2 OJ L 353, 31.12.2008, p. 1.
3 OJ L 235, 05.09.2009, p. 1

(4) In December 2011, the SCCS issued a scientific opinion on Quaternium-15 (cis-isomer)[4], which concluded that the safety of cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride could not be assessed because the available dermal absorption values were not sufficiently reliable to calculate the dermal uptake of cis-CTAC and because the appropriate toxicity studies to establish a reliable No Observed Adverse Effect Level (NOAEL) were unavailable. Therefore, a margin of safety (MoS) could not be calculated. Given the CMR classification of cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride and taking into account the absence of relevant toxicological data, it was considered that the use of this substance in cosmetic products might not be safe for the consumers.

(5) Since the scientific opinion of the SCCS provided no basis to consider the substance as safe for use in cosmetics, the Commission considers that Quaternium-15 represents a potential risk to human health when used in cosmetic products. As a result and aiming to ensure legal clarity regarding the prohibition of this substance, Quaternium-15 should be deleted from Annex V to Regulation (EC) No 1223/2009.

(6) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

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

[4] SCCS/1344/10, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_077.pdf.