Commission Regulation (EU) No 1003/2014 of 18 September 2014 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) No 1003/2014

of 18 September 2014

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(1) thereof,

Whereas:

(1) The mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone with magnesium chloride and magnesium nitrate is currently allowed as a preservative in all cosmetic products at a maximum concentration of 0,0015 % of a mixture in the ratio 3:1 of Methylchloroisothiazolinone (and) Methylisothiazolinone respectively.

(2) The Scientific Committee on Consumer Safety (SCCS) adopted an opinion on the safety of the mixture Methylchloroisothiazolinone (and) Methylisothiazolinone on 8 December 2009[(2)].

(3) The SCCS concluded that the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone in a ratio of 3:1 does not pose a risk to the health of the consumer when used as a preservative up to a maximum authorised concentration of 0,0015 % in rinse-off cosmetic products, apart from its skin sensitising potential. The SCCS indicated that induction and elicitation would be less likely in a rinse-off product than when the same concentration is present in a leave-on product.

(4) The issue of stabilizers for that mixture was addressed by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNPF), subsequently replaced by the Scientific Committee on Consumer Products (SCCP), pursuant to Commission Decision 2004/210/EC[(3)], subsequently replaced by the SCCS, pursuant to Commission Decision 2008/721/EC[(4)], in an opinion of 24-25 June 2003[(5)]. The Committee stated that, taking into account that the active ingredients and their ratio remain unchanged in current commercialised cosmetic products and that the concentration of the stabiliser system in the finished cosmetic products is negligible, the replacement of magnesium chloride and magnesium nitrate by copper sulphate or any other authorised cosmetic ingredient as a stabiliser system in the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone does not alter the

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1003/2014. (See end of Document for details)*

toxicological profile of that mixture. When requested by the Commission to clarify the interpretation of the word 'authorised', the Committee replied, in an opinion of 7 December 2004[6], that the expression 'authorised cosmetic ingredient' should be interpreted as 'any ingredient which, in the light of the Cosmetics Directive[7], is allowed or not prohibited and may be used in cosmetic products, provided that any substance belonging to the classes of ingredients listed in the Annexes III-VII[8] of the Directive may be used only if it is included in the respective annex'. In addition, the conclusion of the SCCS opinion of 8 December 2009 contains an assessment of the safety of the mixture itself and makes no reference to the stabilisers taken into consideration.

(5) In light of the SCCS opinion mentioned above, the Commission considers that, in order to avoid a potential risk to human health, the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone should be restricted as recommended by the SCCS, while the reference to the stabilisers magnesium chloride and magnesium nitrate should be deleted from its chemical name.

(6) It should be clarified that the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product, as it would alter the ratio 3:1 allowed for the mixture[9].

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

(8) The application of the above-mentioned restrictions should be deferred to allow the industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted nine months to place on the market compliant products, and eighteen months to withdraw from the market non-compliant products after the entry into force of this Regulation.

(9) 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

From 16 July 2015 only cosmetic products which comply with Regulation (EC) No 1223/2009 as amended by this Regulation shall be placed on the Union market.

From 16 April 2016 only cosmetic products which comply with Regulation (EC) No 1223/2009 as amended by this Regulation shall be made available on the Union market.

Article 3

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

It shall apply from 16 July 2015.

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

Done at Brussels, 18 September 2014.

For the Commission

The President

José Manuel BARROSO