



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)

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amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

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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(1) thereof,

Whereas:

- (1) The substance 2-Methyl-2H-isothiazol-3-one, which has been assigned the name Methylisothiazolinone under the International Nomenclature of Cosmetic Ingredients (INCI), CAS number 2682-20-4, is currently authorised as a preservative in rinse-off cosmetic products at a concentration up to 0,01 % weight/weight (100 ppm) through entry 57 of Annex V to Regulation (EC) No 1223/2009.
- (2) The Scientific Committee on Consumer Safety (SCCS) adopted an opinion on the safety of Methylisothiazolinone on 15 December 2015². The SCCS concluded that for rinse-off cosmetic products, a concentration up to 0,0015 % (15 ppm) Methylisothiazolinone is considered safe for the consumer from the point of view of induction of contact allergy.
- (3) In light of that SCCS opinion, it is important to address the increased incidence of allergies induced by Methylisothiazolinone and that substance should therefore be further restricted in rinse-off products.
- (4) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (5) The industry should be allowed a reasonable period of time to make the necessary adjustments to product formulations in view of their placing on the market and for the withdrawal of non-compliant products from the market.
- (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:

Article 1

Annex V to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1557/15 (submission III)

Article 2

From [date = 6 months after the date of entry into force] only cosmetic products which comply with this Regulation shall be placed on the Union market.

From [date = 9 months after the date of entry into force] only cosmetic products which comply with 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*.

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