



Council of the
European Union

Brussels, 17 March 2017
(OR. en)

7463/17

MI 248
ENT 72
CONSUM 98
SAN 111
ECO 16
ENV 273
CHIMIE 27

COVER NOTE

From:	European Commission
date of receipt:	16 March 2017
To:	General Secretariat of the Council
No. Cion doc.:	D049873/01
Subject:	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

Delegations will find attached document D049873/01.

Encl.: D049873/01



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)

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 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.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1557/15 (submission III)

- (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.

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