



Brussels, **XXX**  
[...](2016) **XXX** draft

**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

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

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../..

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## amending Annex III 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<sup>1</sup>, and in particular Article 31(2) thereof,

Whereas:

- (1) Zinc Pyrithione is authorised as a preservative in rinse-off hair products at a maximum concentration of 1,0 % and in other rinse-off cosmetic products at 0,5 % (excluding oral products) in entry 8 of Annex V to Regulation (EC) No 1223/2009. Zinc Pyrithione is also regulated in entry 101 of Annex III to Regulation (EC) No 1223/2009 for purposes other than inhibiting the development of micro-organisms in leave-on hair products at a maximum concentration of 0,1 %.
- (2) In 2000, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) was requested to review the safety of Zinc Pyrithione in its function as a non-preservative. On 17 December 2002 the SCCNFP adopted an opinion<sup>2</sup> concluding the safe use of Zinc Pyrithione for non-preservative purposes in cosmetic rinse-off and leave-on hair care products at a maximum concentration of 1,0 % and 0,1 % respectively. The opinion also concluded that Zinc Pyrithione should not be used in products for oral hygiene.
- (3) In 2008, the Scientific Committee on Consumer Safety (SCCS) was requested to evaluate an extension of the maximum concentration from 1,0 % to 2,0 % in rinse-off anti-dandruff hair care products.
- (4) On 18 June 2013 the SCCS adopted an opinion, later revised on 18 June 2014<sup>3</sup>, concluding on the safety of Zinc Pyrithione when used at a concentration up to 2,0 % as an anti-dandruff agent in rinse-off hair care products.
- (5) In light of the opinions mentioned above, Zinc Pyrithione should be authorised in rinse-off anti-dandruff hair products at a maximum concentration of 2,0 % for non-preservative purposes.
- (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,

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> SCCNFP/0671/03

<sup>3</sup> SCCS/1512/13: [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_133.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_133.pdf)

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III 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*