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Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Delegations will find attached document D039970/04.

Encl.: D039970/04



Brussels, **XXX**
[...] (2015) **XXX** draft

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

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) .../...

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)

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 (2) thereof,

Whereas:

- (1) On 27 March 2014, the Scientific Committee on Consumer Safety ("SCCS") issued a scientific opinion on potassium hydroxide², which concluded that potassium hydroxide is safe for use as a callosity softener/remover up to a maximum concentration of 1,5 % w/w.
- (2) The SCCS also concluded that the safe use of cosmetic products containing free potassium hydroxide in concentrations from 0,5 % w/w depends on responsible risk management, through warnings and extensive guidance for use.
- (3) Following the scientific opinion of the SCCS, the Commission considers that potassium hydroxide should be considered safe for use as a callosity softener/remover up to a maximum use concentration of 1,5 % w/w.
- (4) In light of the conclusion of the SCCS regarding responsible risk management with respect to products containing free potassium hydroxide in concentrations from 0,5 % w/w, the Commission considers that cosmetic products containing potassium hydroxide for use as a callosity softener/remover should bear a warning referring to the directions for use.
- (5) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

¹ OJ L 342, 22.12.2009, p. 59

² SCCS/1527/14, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_154.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*