

Commission Regulation (EU) 2016/622 of 21 April 2016 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) 2016/622

of 21 April 2016

amending Annex III 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 products⁽¹⁾, 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 hydroxide⁽²⁾, 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,

HAS ADOPTED THIS REGULATION:

Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) 2016/622, Introductory Text. (See end of Document for details)

- (1) [OJ L 342, 22.12.2009, p. 59.](#)
- (2) [SCCS/1527/14, sccs_o_154.pdf](#) http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/

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