Commission Regulation (EU) No 483/2013 of 24 May 2013 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) No 483/2013

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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[(1)], and in particular Article 31(1) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

(1) The Scientific Committee on Consumer Products ('SCCP'), subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS') pursuant to Commission Decision 2008/721/EC of 5 September 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC[(2)], concluded in its opinion of 2 October 2007 that the data included in the dossier demonstrate that polidocanol is of low toxicity and does not pose a risk to the health of the consumer when used up to 3 % in leave-on and up to 4 % in rinse-off cosmetic products. In addition, the SCCP maintained that recent scientific evidence did not confirm the assumed local-anaesthetic effect of polidocanol. Thus, its presence in cosmetics and skin care products will not affect cutaneous sensation. It should therefore be included in Annex III to Regulation (EC) No 1223/2009.

(2) The SCCS, in an Addendum of 13-14 December 2011 to the SCCP opinion on polidocanol, confirmed the conclusions of the SCCP.

(3) Given that polidocanol was found in both injectable and topical medicinal products at concentrations even lower than the ones considered safe by the SCCP, the Commission requested the opinion of the European Medicines Agency on the classification of topical products containing the substance. The opinion, formulated by the Committee for Medicinal Products for Human Use on 25 October 2011, concluded that products containing polidocanol do not automatically qualify as medicinal products falling under the definition of medicinal product provided in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(3)]. In addition, polidocanol used in

topical products at the suggested concentrations and for the suggested topical use (3 % for leave-on products and 4 % for rinse-off products) acts as detergent or ionic surfactant and these products do not present the characteristics of medicinal products.

(4) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(5) The application of the abovementioned restrictions should be deferred by 12 months to allow the industry to make the necessary adjustments to product formulations.

(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 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*.

It shall apply from 1 April 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 May 2013.

For the Commission

The President

José Manuel BARROSO