

Commission Regulation (EU) 2016/314 of 4 March 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) 2016/314

of 4 March 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)

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,

Whereas:

- (1) The substance Diethylene Glycol Monoethyl Ether (DEGEE) with the INCI name Ethoxydiglycol which is used in cosmetic products is not yet regulated under Regulation (EC) No 1223/2009.
- (2) DEGEE was the subject of a risk assessment done by France on the basis of which France decided⁽²⁾ that it is safe for consumers, when used in a concentration up to 1,5 % in all cosmetics products except products for oral hygiene. This decision was notified to the Commission and the Member States in accordance with Article 12 of Council Directive 76/768/EEC⁽³⁾. As a result, the Commission gave a mandate to the Scientific Committee on Consumer Products (SCCP) to issue an opinion on the safety of each of the glycolethers restricted by the French decision.
- (3) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety (SCCS) pursuant to Commission Decision 2008/721/EC⁽⁴⁾, adopted scientific opinions on DEGEE, on 19 December 2006⁽⁵⁾, 16 December 2008⁽⁶⁾, 21 September 2010⁽⁷⁾ and 26 February 2013⁽⁸⁾.
- (4) The SCCS concluded that the use of DEGEE in oxidative hair dye formulations at a maximum concentration of 7 % w/w, in non-oxidative hair dye formulations at a maximum concentration of 5 % w/w and in other rinse-off products at a maximum concentration of 10 % w/w does not pose a risk to the health of consumers. The SCCS also concluded that the use of DEGEE does not pose a risk to the health of consumers at a maximum concentration of 2,6 % w/w in other non-spray cosmetic products and in the following spray products: fine fragrances, hair sprays, antiperspirants and deodorants. However, the use of DEGEE in oral hygiene products and eye products has not been assessed by the SCCS and thus cannot be considered safe for consumers.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2016/314. (See end of Document for details)

- (5) In light of those SCCS opinions, the Commission considers that the non-regulation of DEGEE raises a potential risk to human health.
- (6) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (7) The application of the abovementioned restrictions should be deferred to allow industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted 12 months to place on the market compliant products and to withdraw from the market non-compliant products after the entry into force of this Regulation.
- (8) 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

From 25 March 2017 only cosmetic products which comply with this Regulation shall be placed and 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, 4 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

In Annex III to Regulation (EC) No 1223/2009, the following entry is added:

Ref. No	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/ INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
x	2-(2-ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE)	Ethoxydiglycol	16090-0	203-919-7	(a)	Oxidative hair dye products	(a) to 7% (e):	The level of ethylene glycol impurity in Ethoxydiglycol must be $\leq 0,1$ %. Not to be used in eye products and oral products.
					(b)	Non-oxidative hair dye products	5%	
					(c)	Rinse-off products other than hair dye products	10%	
					(d)	Other non-spray cosmetic products	2,6%	
					(e)	Other following spray products: fine fragrances, hair sprays, antiperspirants	2,6%	

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					and deodorants	
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- (1) [OJ L 342, 22.12.2009, p. 59.](#)
- (2) Ministère de la Santé et des Solidarités. Décision du 23 novembre 2005 soumettant à des conditions particulières et à des restrictions la fabrication, le conditionnement, l'importation, la distribution en gros, la mise sur le marché à titre gratuit ou onéreux, la détention en vue de la vente ou de la distribution à titre gratuit ou onéreux et l'utilisation de produits cosmétiques contenant certains éthers de glycol, Journal officiel, n° 291 du 15 décembre 2005, <http://www.journal-officiel.gouv.fr/frameset.html>
- (3) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ([OJ L 262, 27.9.1976, p. 169](#)).
- (4) 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 ([OJ L 241, 10.9.2008, p. 21](#)).
- (5) SCCP/1044/06, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_082.pdf
- (6) SCCP/1200/08, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_161.pdf
- (7) SCCS/1316/10, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_039.pdf
- (8) SCCS/1507/13, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_119.pdf

Changes to legislation:

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