Commission Regulation (EU) No 1197/2013 of 25 November 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 1197/2013

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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(1) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

(1) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, subsequently replaced by the Scientific Committee on Consumer Products ('SCCP'), pursuant to Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment[(2)], concluded that the potential risks of the use of hair dyes were of concern. The SCCP, in its opinions, recommended that the Commission take further steps to control the use of hair dye substances.

(2) The SCCP further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity or mutagenicity.

(3) Following the opinions of the SCCP, the Commission agreed with Member States and stakeholders on an overall strategy to regulate substances used in hair dye products according to which the industry was required to submit files, containing updated scientific data on the safety of hair dye substances, for a risk assessment by the SCCP.

(4) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS') pursuant to Commission Decision 2008/721/EC of 5 August 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[(3)], assessed the safety of individual substances for which updated files had been submitted by the industry.

(5) As regards the evaluation of possible consumer health risks by reaction products formed by oxidative hair dye substances during the hair dyeing process, based on the data yet available, the SCCS, in its opinion of 21 September 2010, did not raise any major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the Union.

(6) In order to ensure the safety of hair dye products for human health it is appropriate to limit the maximum concentrations of 21 assessed hair dye substances and to list them in Annex III to Regulation (EC) No 1223/2009, by taking into account the final opinions given by the SCCS on their safety.

(7) Following the assessment by the SCCS concerning the substance Toluene-2,5-Diamine, listed in entry 9a of Annex III to Regulation (EC) No 1223/2009, it is appropriate to change the maximum authorised concentrations thereof in the finished cosmetic product.

(8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded its application on eyelashes. This exclusion was motivated by the fact that the level of risk is different when cosmetic products are applied on the hair on the head and on eyelashes respectively. A specific safety assessment was therefore needed for the application of hair dye substances on eyelashes.

(9) The SCCS, in its opinion on oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes of 12 October 2012, concluded that oxidative hair dye substances p-Phenylenediamine, Resorcinol, 6-Methoxy-2-Methylamino-3-Aminopyridine HCl, m-Aminophenol, 2-Methyl-5-Hydroxyethyl Aminophenol, 4-Amino-2-Hydroxytoluene, 2,4-Diaminophenoxyethanol HCl, 4-Amino-m-Cresol, 2-Amino-4-Hydroxyethylaminoanisole and 2,6-Diaminopyridine, listed in Annex III to Regulation (EC) No 1223/2009 and found safe for use in hair dye products, can be safely used by professionals in products intended for colouring eyelashes. In addition, the SCCS concluded that up to 2 % of hydrogen peroxide, which is listed under entry 12 in Annex III to Regulation (EC) No 1223/2009, can be considered safe for consumers when applied on eyelashes.

(10) On the basis of the scientific assessment of those substances their use should be allowed in products intended for colouring eyelashes in the same concentrations as in hair dye products. However, in order to avoid any risk connected with the self-application of products intended for colouring eyelashes by consumers, they should be allowed for professional use only. In order to allow professionals to inform consumers about possible adverse effects of eyelash colouring and to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.

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

(12) In order to avoid a disruption on the market due to the transition from Council Directive 76/768/ECC of 27 July 1976 on cosmetic products[(4)] to Regulation (EC) No 1223/2009, this Regulation should apply from the same date as Regulation (EC) No 1223/2009.

(13) A sufficient transition period should be granted to economic operators in order to comply with the new warnings for products intended for colouring eyelashes.

(14) 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 day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 11 July 2013.

However, the following provisions in the Annex shall apply from 1 July 2014:

(a) the provisions in column ‘i’ of point 1 and of points 3 to 9 relating to the use of the substances in products intended for colouring eyelashes;

(b) points 2 and 10.

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

Done at Brussels, 25 November 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex III to Regulation (EC) No 1223/2009 is amended as follows:

(1) the following entry 8b is inserted:

a	b	c	d	e	f	g	h	i
‘8b	p-Phenylenediamine and its salts	p-Phenylenediamine; p-Phenylenediamine HCl; p-Phenylenediamine Sulphate	106-50-3; 624-18-0; 16245-77-5	203-404-7; 210-834-9; 240-357-1	Products intended for colouring eyelashes		After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 2 % calculated as free base For professional use only.	To be printed on the label: The mixing ratio. For professional use only.  This product can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary ‘black henna’ tattoos may increase the risk of allergy.

								Eyelashes shall not be coloured if the consumer: — has a rash on the face or sensitive, irritated and damaged scalp, — has experienced any reaction after colouring hair or eyelashes, — has experienced a reaction to a temporary ‘black henna’ tattoo in the past. Rinse eyes immediately if product comes into contact with them. Contains phenylenediamines.