Commission Regulation (EU) 2017/237 of 10 February 2017 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) 2017/237

of 10 February 2017

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) 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[(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 carcinogenicity.

(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[(3)], assessed the safety of individual hair dye 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/237. (See end of Document for details)*

(6) In order to ensure the safety of hair dye products for human health, it is appropriate to set up maximum concentrations of ten assessed hair dye substances by taking into account the final opinions given by the SCCS on their safety.

(7) Since substances N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine and 2,6-Dihydroxyethylaminotoluene are currently regulated under generic entries 8 and 9 of Annex III to Regulation (EC) No 1223/2009, separate reference numbers should be created for those substances, taking into account conclusions on their safety in the SCCS opinions 1572/16 and 1563/15.

(8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded the application of hair dye substances on eyelashes. That 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 25 March 2015 (SCCS/1553/15), concluded that oxidative hair dye substances Toluene-2,5-Diamine, p-Aminophenol, 2-Methylresorcinol, Tetraaminopyrimidine Sulfate, Hydroxyethyl-p-Phenylenediamine Sulfate and 2-Amino-3-Hydroxypyridine, 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.

(10) On the basis of the scientific assessment of those substances, their use should be allowed in products intended for colouring eyelashes. 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 the application of products intended for colouring eyelashes 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) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new requirements and to phase out products concerned which do not comply with those requirements.

(13) 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*.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2017/237. (See end of Document for details)*

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

Done at Brussels, 10 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/237. (See end of Document for details)*

ANNEX

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

(1) The following entry is inserted as reference number 8c:

Reference number	Substance identification				Restrictions			Wordings 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 use preparation	Other	
a	b	c	d	e	f	g	h	i
‘8c	Ethanol, 2,2′-[(2-nitro-1,4-phenylene)diimino]bis- (9CI)	N,N′-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine	84041-77-2	281-856-4	(a) dye substance in oxidative hair dye products	Hair	(a) from 3 September 2017, after mixing under oxidative conditions: As the maximum concentration applied to hair must not exceed 1,0 % For (a) and (b), as from 3 September 2017: — Do not use with nitrosating agents. — Maximum nitrosamine content: 50 μg/kg. — Keep away from eyes.	(a) As from 3 March 2018, to be printed on the label: The mixing ratio. ⚠ Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on children under 16 years of age. Temporary black henna’ tattoos may
					(b) dye substance in non-oxidative hair dye products	(b) Hair from 3 September 2017: 1,5 %		

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								increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary ‘black henna’ tattoo in the past’.

(2) the text in entry 9, column b, is replaced by the following:

> Methylphenylenediamines, their N-substituted derivatives and their salts ([1]) with the exception of the substances under reference numbers 9a and 9b of this Annex and substances under reference numbers 364, 1310 and 1313 in Annex II;

(3) the entry 9a is replaced by the following: