Commission Regulation (EU) 2015/1190 of 20 July 2015 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) 2015/1190

of 20 July 2015

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) Following the 2001 scientific study 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 takes 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 substances for which updated files had been submitted by the industry.

(5) Taking into account the final opinions given by the SCCS on the safety of individual substances, it is appropriate to limit the maximum concentrations of nine assessed hair dye substances and to list them in Annex III to Regulation (EC) No 1223/2009.

(6) 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/1190. (See end of Document for details)*

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.

(7) The sensitising potential of individual hair dye substances has been addressed in their risk assessments by the SCCS. In order to better inform the consumer about possible adverse effects of hair dye use and to lower the risk of sensitisation to hair dye products among consumers, appropriate warnings should be printed on the label of oxidative hair dye products and of non-oxidative hair dye products containing hair dye substances with an extreme or strong sensitising potential.

(8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded its application 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. A specific safety assessment was therefore needed for the application of thioglycolic acid and its salts on eyelashes.

(9) The SCCS, in its opinion on thioglycolic acid and its salts of 11 November 2013, concluded that the general use (personal use by consumers at home) of products intended for eyelash-waving containing thioglycolic acid and its salts is not recommended because of the risk of eye irritation during self-application. However, the concentration of thioglycolic acid and its salts in those products is safe up to 11 % when applied on eyelashes by a professional which reduces the risk of a direct contact with the eyes. In addition, the SCCS concluded that the use of thioglycolic acid and its salts up to 5 % is safe for use as a depilatory when used as intended. The safety of these types of cosmetic products highly depends on responsible risk management including warnings and extensive guidance for use.

(10) On the basis of the scientific assessment of thioglycolic acid and its salts their use should be allowed in products intended for eyelash waving and for use as depilatories. However, in order to avoid any risk connected with the self-application of products intended for eyelash-waving 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 containing thioglycolic acid and its salts on eyelashes and to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.

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

(12) The application of the restrictions relating to hair dye substances should be deferred to allow the industry to comply with the requirements for hair dye products. 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.

(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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/1190. (See end of Document for details)*

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 10 August 2015, except the provisions in point 2 of the Annex which shall apply from 10 August 2016.

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

Done at Brussels, 20 July 2015.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) entry 2a is replaced by the following:

a	b	c	d	e	f	g	h	i
‘2a	Thioglycolic acid and its salts	Thioglycolic acid	68-11-1	200-677-4	(a) hair waving or straightening products	(a) 11 %	(a) ready for use pH 7 to 12,7	Conditions of use: (a) (b) (c) (d) Avoid contact with eyes Rinse eyes immediately if product comes into contact with them. (a) (c) (d) Wear suitable gloves Warnings to be printed on the label: (a)(i) (b) (c) Contains thioglycolate Follow the instructions Keep out of reach of children (a)(ii) (d) For professional use only
					(b) depilatories	(b) 5 %	(b) ready for use pH 7 to 12,7	
					(c) hair rinse-off products	(c) 2 %	(c) ready for use pH 7 to 9,5	
					(d) intended for eyelash waving	(d) 11 % The abovementioned percentages are calculated as thioglycolic acid	(d) professional use ready for use pH 7 to 9,5	

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								Contains thioglycolate Follow the instructions’

(2) the following entries 288 to 296 are added:

a	b	c	d	e	f	g	h	i
‘288	3-[(4-amino-3-methyl-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]-N,N,N-trimethylpropan-1-aminium, methylsulfate salt	HC Blue No 17	16517-75-6	405-392-2	(a) (b)	Hair dye substance in oxidative hair dye products Hair dye substance in non-oxidative hair dye products	(a) 2,0 % (after mixing under oxidative conditions) the maximum concentration applied to hair must not exceed 2,0 % For (a) and (b): — Do not use on persons under 16 years of age. Keep out of reach of children — Do not use on persons suffering from allergic contact dermatitis — Do not use on persons with a history of adverse reactions to temporary “black henna” tattoos — Keep in your first-aid container Do not colour your hair if: — you have a rash on your	(a) To be printed on the label: The mixing ratio. Read and follow instructions. This product is not intended for use with persons under 16 years of age. Maximum nitrosamine content: 50 µg/kg. Keep out of reach of children. Do not colour your hair if: — you