Commission Regulation (EU) 2020/1683 of 12 November 2020 amending Annexes II and 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) 2020/1683

of 12 November 2020

amending Annexes II and 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 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 health risks of the use of hair dyes were of concern.

(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) Having succeeded the SCCP pursuant to Commission Decision 2008/721/EC[(3)], the Scientific Committee on Consumer Safety (SCCS) assessed the safety of individual hair dye substances for which updated files had been submitted by the industry.

(5) As a result of the assessement by the SCCS, in order to ensure the safety of hair dye products for human health it is necessary to prohibit the use of three hair dye substances, 1,2,4-Trihydroxybenzene[(4)], 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid[(5)] and 4-Amino-3-hydroxytoluene[(6)], based on the final opinions given by the SCCS on their safety. In addition, in light of the final opinions by the SCCS on other six hair dye substances, Dimethylpiperazinium Aminopyrazolopyridine HCl[(7)], Methylimidazoliumpropyl p-phenylenediamine HCl[(8)], HC Orange No 6[(9)], Acid

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Orange 7[10], Tetrabromophenol Blue[11] and *Indigofera Tinctoria*[12], it is appropriate to limit their maximum concentrations for use in hair dye products.

(6) The definition of a hair product laid down in point (1)(c) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009 excludes the application of hair dye substances on eyelashes, based on a different level of risk of applying a cosmetic product on the hair on the head as compared to applying the same product on eyelashes. A specific safety assessment was therefore needed for the application of hair dye substances on eyelashes.

(7) The substance 2-Methoxymethyl-p-Phenylenediamine and its sulfate are listed under entry 292 in Annex III to Regulation (EC) No 1223/2009. Taking into account the conclusions of the latest SCCS opinion[13] on the use of those substances on eyelashes, the field of application of the restriction to which they are subject should be extended to products intended for colouring eyelashes.

(8) In order to avoid any risk related to self-application by consumers of products intended for colouring eyelashes that contain 2-Methoxymethyl-p-Phenylenediamine and its sulfate, those products should be allowed for professional use only.

(9) In order to inform consumers and professionals about possible adverse effects of the use of hair dyes and products intended for colouring eyelashes with the aim to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.

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

(11) 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 cosmetic products which do not comply with those requirements.

(12) 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

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*.

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

ANNEX

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

(1) in Annex II, in the table, the following entries are added:

Reference number	**Substance identification**		
	Chemical name/ INN	**CAS number**	**EC number**
‘1642	1,2,4-Trihydroxybenzene[a] when used as a substance in hair and eyelash dye products	533-73-3	208-575-1
1643	4-Amino-3-hydroxytoluene[a] when used as a substance in hair and eyelash dye products	2835-98-5	220-620-7
1644	2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid[a] when used as a substance in hair and eyelash dye products	117907-43-4	411-260-3

a From 3 September 2021 hair and eyelash dye products containing those substances shall not be placed on the Union market.
From 3 June 2022 hair and eyelash dye products containing those substances shall not be made available on the Union market.’;

(2) in Annex III, the table is amended as follows:

(a) entry 292 is replaced by the following:

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**	
‘292	1,4-Benzenediamine, 2-(methoxymethyl)- 1,4-Benzenediamine,	2-Methoxymethyl-p-Phenylenediamine 2-Methoxymethyl-	337906-36-2 337906-37-3	692-526-3 683-749-6	(a)	Hair dye substance in oxidative hair	(a) (b)	(a) After mixing under oxidative conditions the	To be printed on the label:

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	2-(methoxymethyl)-p-phenylenediamine sulfate	p-Phenylenediamine Sulfate			(b)	dye products Products intended for colouring eyelashes	(b)	maximum concentration applied to hair or eyelashes must not exceed 1,8 % (calculated as free base) Professional use	The mixing ratio. ‘⚠Hai colorants can cause severe allergic reactions Read and follow instructio This product is not intended for use on persons under the age of 16. Tempora “black henna” tattoos may 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 experienc any reaction after colouring your hair,
										—	you have experienc a reaction to a temporar “black henna” tattoo in the past.’
									(b)	To be printed on the label: The mixing ratio.	‘Thi product can cause severe allergic reactions Read and follow instructio This product is