Commission Regulation (EU) No 658/2013 of 10 July 2013 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) No 658/2013

of 10 July 2013

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 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) Regulation (EC) No 1223/2009 replacing Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽²⁾ will apply from 11 July 2013.
- (2) Annexes II and III to Directive 76/768/EEC were amended by Commission Implementing Directive 2012/21/EU⁽³⁾ after the adoption of the Regulation, by including one hair dye substance into Annex II, 26 hair dye substances into Part 1 of Annex III and by changing the maximum authorised concentrations in the finished cosmetic product for two hair dye substances in Part 1 of Annex III. Those amendments should now be reflected in Regulation (EC) No 1223/2009.
- (3) In accordance with Implementing Directive 2012/21/EU, Member States are to apply the laws, regulations and administrative provisions adopted in order to comply with that Directive from 1 September 2013. Therefore, this Regulation should apply from that date.
- (4) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (5) 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 U.K.

Annexes II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.



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 1 September 2013.

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

Done at Brussels, 10 July 2013.

For the Commission The President José Manuel BARROSO

ANNEX U.K.

Annexes II and III to Regulation (EC) No 1223/2009 are amended as follows:

(1) In Annex II, the following entry is added:

Reference number	Substance identification							
	Chemical name/ INN	CAS number	EC number					
°1373	N-(2-Nitro-4- aminophenyl)- allylamine (HC Red No 16) and its salts	160219-76-1'						

- (2) Annex III is amended as follows:
 - (a) The following entries concerning reference numbers 198 to 200 are added:

Refere	n Sa ıbsta	nce ider	ntificatio	on	Restri	ctions		Wording
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	name/			ernumbe	ertype,	concer	itration	conditions
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						prepa	ration	warnings
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					temporary
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					henna'
					tattoo
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					Hair
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							cause severe allergic reactions.
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									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. Hair colorants can cause severe allergic reactions.
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								your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past.'
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(b) The following entries concerning reference numbers 206 to 214 are added:

206	3-(2- Hydrox y238411-2298-		After To be
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risk of allergy. Do not colour your hair if: — you have a rash

207 1H	I- Dihydro&Wind	l6124012-130-9		
	dole-5,6-	(á)	Hair (a) dye substance in oxidative hair dye products	(a) fter To mixing be under printed oxidativen conditionse the label: Timaximum neixingentration
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							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. Hair colorants can cause severe allergic reactions.
208	5- 4Amino- 2Chloro- benol 1 Øritse l HCl	-85-7	Hair dye substan in oxidativ hair dye product	/e	After mixing under oxidativ condition the maximu concent applied to hair must not exceed 1,5 % (calcular)	offshe mixing matio. I Read and	Dns.

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								a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
209	1H- Indol-6 ol	6- - Hydrox	5411 7-020	0Hair dye substan in oxidativ hair dye product	ve	After mixing under oxidativ conditio the maximu concent applied to hair must not exceed 0,5 %	on the dabel: offshe mixing natio.	



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								reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
211	2- Aminop ol	2- y ridin eð Hydrox	024D-886	6 H &air dye substan in oxidativ hair dye product	ve	After mixing under oxidativ condition the maximu concent applied to hair must not exceed 1,0 %	offshe mixing I na tio.	



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									any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
213	1- Hydrox methyli	2- yMethyl- aphphalo	-1-	7241-265	H2air dye substan in oxidativ hair dye product	ve	under oxidativ condition the maximu concent applied to hair must not exceed 2,0 % (When both 2- Methyl- Naphth and 1- Acetoxy	rishe mixing matio. Read and follow instruction This product intended yf <u>9</u> maphifiale: persons	

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								colorants can cause severe allergic reactions.
214	Disodiu 5,7- dinitro- oxido-2 naphtha CI 10316	Yellow 81	&12-69()-2 (a)	Hair dye substa in oxidat hair dye produc	ive	oxidativ condition the Tilmaximu ncixingnt ratipplied	printed on bls e label: im ration
				(b)	(b Jair dye substa in non- oxidat hair dye produc	ive		S S DNS.

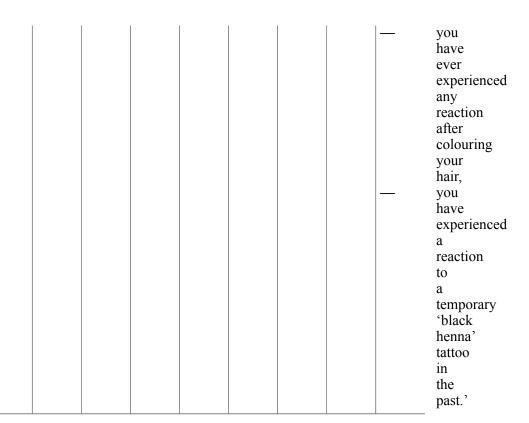
							risk of allergy. Do not colour your hair if: 	you have a rash on your face or sensitive, irritated and damaged scalp, you have ever experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past.'
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(c)

The entry with reference number 240 is replaced by the following:

240	4-	4-	99-56-9	202-76	5 H3 air		After	To be
	Nitro-1	Nitro-			dye		mixing	printed
	phenyle	nediami			substan	ce	under	
		Phenyle	enediami	ne	in		oxidativ	
					oxidativ	ve	conditio	offshe
					hair			mixing
							maximu	i na tio.

			dye product	S	concent applied to hair must not exceed 0,5 %		ons.
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(d) The entry with reference number 251 is replaced by the following:

251	2 (1	НС	24005	8246-52	Lanir	1,0 %		•
231	2-(4- Amino-		24903-0	5 24 0-32		1,0 %		\wedge
					dye			/ · \
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					oxidativ	ve		agents
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								Read [−]
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								instructions.
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> age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: you have а rash on your face or sensitive, irritated and damaged scalp, you have ever experienced any reaction after colouring your hair, you have experienced а reaction to а temporary **'black** henna' tattoo in the past.'

(e) The entry with reference number 253 is replaced by the following:

Commission Regulation (EU) No 658/2013. (See end of Document for details)

253	2-	HC	59820-4	4 3-28 -840) H air	1,5 %		Do
	[bis(2-	Yellow			dye	-		not
	Hydrox	yNetth∳l)a	mino]-5·		substan	ce		use
	nitroph	enol			in			with
					non-			nitrosating
					oxidativ	<i>r</i> e		agents
					hair		—	Maximum
					dye			nitrosamine
					product	S		content:
								50 μg/
								kg
							—	Keep
								in
								nitrite-
								free
								containers

(f) The entries with reference numbers 255 and 256 are replaced by the following:

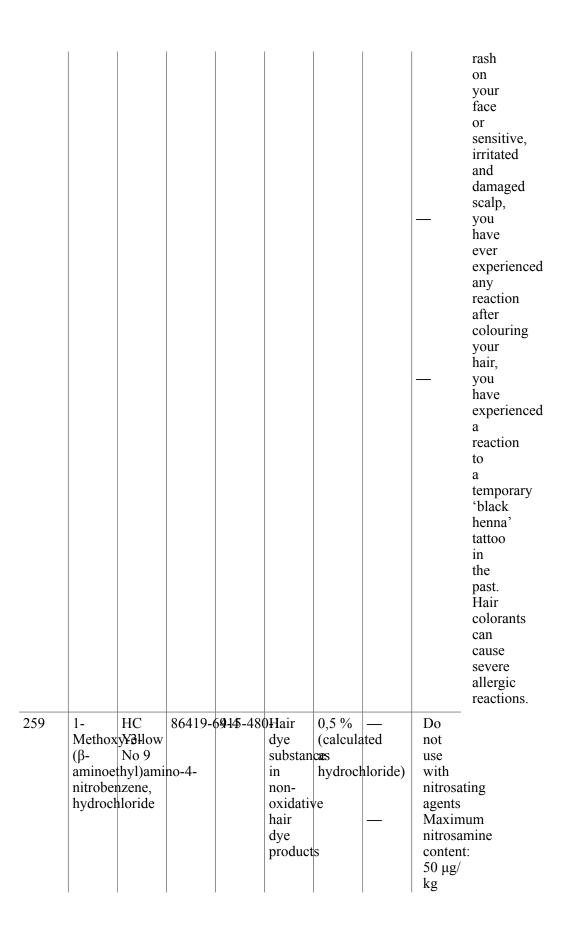
						1	1		
255	2-[(2- Nitron	HC heYiey111)aww		5 202 5-555 nol	5-8 (a)	Hair	(a)	(aA) fter	То
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							cause severe allergic reactions.
256	4-[(2- Nitroph	HC Coya)nge No 1	0 859-13 2 101	2Hair dye substan in non- oxidativ hair dye product	ve		

(g) The following entries concerning reference numbers 258 to 264 are added:

258	2-	HC	2784-89	92620-494		1,0 %	^	
	Nitro-	Red			dye			
	N1-	No 1			substan	ce	/! \	
	phenyl-	-			in		/ • \	
	benzen	e-1,4-			non-			
	diamine	e			oxidativ	ve	Read	
					hair		and	
					dye		follow	
					product	s	instructions.	
					1		This	
							product	
							is not	
							intended	
							for	
							use on	
							persons	
							under	
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							age of	
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							Temporary	
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							ha	ve
							a	



260	1-(4'- Aminop methyl- (bis-2- hydrox aminob	yethyl)	0)-2-	- 24 63420	dye substan in non- oxidativ hair dye product	ve		Keep in nitrite- free containers
261	N-(2- Hydrox nitro-4- trifluori aniline		10442-8	8348-76)-2 (a) (b)	Hair dye substa in oxidat hair dye substa in non- oxidat hair dye produc	ive 2,5 % nce For (a) and (b):	(a) fter To mixing be under printed oxidativen conditiontse the label: Timaximum neixinegntration ratioplied Read% and follow instructions. This product is uset intended for

				risk of allergy.	
				Do not	
				colour your	
				hair if:	
					you
					have
					a
					rash
					on vour
					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.
					Hair
					colorants
					can
					cause
					severe allergic
					reactions.

262	Benzen	a Braisnin ann	,68391-3	3 2 69-943	3 H5 air	2,0 %		
	3-	Yellow			dye			
	[(4,5-	57			substan	ce		
	dihydro	-3-			in			
	methyl	5-			non-			
	oxo-1-				oxidativ	<i>r</i> e		
	phenyl-	-1H-			hair			
	pyrazol	-4-			dye			
	yl)azo]				product	S		
	N,N,Nt	rimethyl	-,		-			
	chlorid	e						
263	Ethano	l,Dispers	e20721-:	50403-981	7 H5 air	0,3 %		
	2,2'-	Black			dye	(of the		
	[[4-	9			substan	conixture		
	[(4-				in	in the		
		henyl)az	o]pheny	[]imino]	omson-	ratio		
					oxidativ	∕∎:1 of		
					hair	2,2'-		
					dye	[4-(4-		
					product		henylazo)phenylimino]diethanol
					-	and	-	-
						lignosu	lfate)	
264	9,10-	НС	99788-′	7\$1271-470) H air	0,3 %		Do
	Anthra	Bilenction	e,		dye			not
	1,4-	No 14			substan	ce		use
	bis[(2,3	5-			in			with
		xypropy	l)amino	-	non-			nitrosating
			-		oxidativ	<i>r</i> e		agents
					hair		—	Maximum
					dye			nitrosamine
					product	s		content:
					•			50 μg/
								kg
							_	Keep
								in
								nitrite-
								free
		1	1	1		1		containers

(h) The entries with reference numbers 16, 22, 221, 250 are replaced by the following:

Refere	nSubstance identification				Restri	Wording		
numbe	rChemi name/ INN	caName of Comm Ingred Glossa	numbe ion lients	EC ernumb		ctMaxin concer in ready use prepai	itration	of conditions of use and warnings
ʻ16	1- Naphth	1- a Neaph th		201-96	Hair dye		After mixing	To be printed

	substan	ce	under	on the	
	in		oxidativ	veahel.	
	oxidativ	10	conditio	The	
		/e			
	hair			mixing	
	dye		maximu	ı na tio.	
	product	S	concent	I A	
	I		applied		
			to hair	/• \	
				/ 1	\
			must	/•	\
			not	D 1	
			exceed	Read	
			2,0 %	and	
			2,0 /0	follow	
				instructio	ns
				This	110.
				product	
				is not	
				intended	
				for	
				use on	
				persons	
				under	
				the	
				age of	
				16.	
				Tempora	ry
				'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,
				<u> </u>	you
					have

									ever experience any reaction after colouring your hair, you have experience a reaction to a temporar 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions	g ced y
22	1,3- benzene	Resorci	nb08-46-	2 03-585	5-2 (a) (b)	Hair dye substa in oxidat hair dye produc (b)air lotions and shamp	2. ive For 1 and 2: thatfer mixing under oxidativ condition the maximu concent applied	ns Im	1. ional	To be printed on the label: The mixing ratio. Read and follow
							to hair must not exceed 1,25 %			instruction 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: ____

mixing ratio. For									2.	ratio. For professio
-------------------------	--	--	--	--	--	--	--	--	----	----------------------------

> Contains resorcinc Rinse eyes immedia if product comes into contact with them. Hair 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: (b) Contains resorcinol. Hydroxyk0004118-3085090-7 (a) 2-(4-То Hair (a) fter (a) Methyl-Nitrodye mixing be nitroanilimo)ethanol substance under printed Toluidine oxidativon in oxidative conditiontse hair the label: maximum

221

		dye		Temencent	ration
		produc	ets	n aipxpihig d r atti o.	
	(b)	(Hair	1,0 %	Λ	
		dye substa	nce	/• \	`
		in		/ :	7
		non-	Ear (a)	Read ^{1,0,70}	
		oxidat	i∳er (a) and	and	
		hair dye	(b):	follow	
		produc		instructio	ons.
		I		This	
				product is not	
				intended	ina
				for agents	ing
				use on Maxim	um
				persons	nine
				under content	:
				the μg/ age of	
				Reep Tempora	ry
				, nitrite-	
				henna' free tattoos	
				tattoos. containe may	ers
				increase	
				your	
				risk of	
				allergy. Do not	
				colour	
				your	
				hair if:	
				<u> </u>	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. Hair colorants can cause severe allergic reactions.
250	chlorob + 1,4- bis- (2',3'-	No 10 + HC xypptopy etvæhte	95576-8 + 95576-9 1)amino-	92-4 -5-	(a) (b)	Hair dye substa in oxidat hair dye produc (bJair dye substa in non- oxidat hair dye produc	ive 2,0 % nce For (a) and	(a) fter mixing under oxidativ condition the Timaximu nixingnt ratioplied exceed Half % colorants can cause severe allergic reactions Readh and rosatt follows, instruction	printed on offse label: im ration

	1	I	I I			The	100
					—	T Ma ximu	
						p notrosa n	
						iscontent:	
						inft@nde/d	
						folag	
						ukcep	
						piersons	
						uniteite-	
						thee	
						agontaine	.
							515
						16. T	
						Tempora	ry
						'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,
						<u> </u>	you
							have
							ever
							experienced
							any
							reaction
							after
							colouring
							your
							hair,
							you
							have
							experienced
							a
							reaction
							to

					a temporary 'black henna' tattoo in the past.'
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- (1) OJ L 342, 22.12.2009, p. 59.
- (**2**) OJ L 262, 27.9.1976, p. 169.
- (**3**) OJ L 208, 3.8.2012, p. 8.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013.