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

Annexes II and III to Regulation (EC) No 1223/2009 are 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 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

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

ANNEX

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

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

Reference	Substance identification							
number	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:

	n&ubsta				Restri			Wording
numbe	rChemi	c a Name		EC		ctMaxin	nuOnther	of
	name/	of	numbe	ernumbe	ertype,	concer	tration	conditions
	INN	Comm	ion		body	in		of
		Ingred	lients		parts	ready		use
		Glossa	ry		_	use		and
						prepai	ation	warnings
198	2,2'-	N,N-	54381-	1 859 -134	4 ₩ air		After	To be
	[(4-	bis(2-			dye		mixing	printed
	Amino	o lh Evocholo ix	wintbyb)s	(ethanol)	substan	ce	under	on the
	sulphat			Ì	in		oxidativ	deabel:
	•	Phenyle	nediami	ne	oxidativ	/e	condition	offshe
		Sulfate			hair		the	mixing
					dye		maximu	ı na tio.
					product	S	concent	
					•		applied	/\
							to hair	/ • \
							must	/ : \
							not	
							exceed	Read
							2,5 %	and
							(calcula	ited low .
							0.0	mon actions
							sulphate	e) his
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								under Maximum
								the nitrosamir
								age of
								16.

youtainers 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 experience any reaction after colouring your hair, — you have experience any reaction after colouring your hair, — you have experience in to a reaction to a temporary black henna' tattoo in the past. Hair colorants can		
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								cause severe allergic reactions.
199	1,3-Benzen 4-chloro-	4- e Chi lbron	3 202-462 1	240air dye substan in oxidativ hair dye product	ve	After mixing under oxidative conditions the maximum concent applied to hair must not exceed 2,5 %	offshe mixing i na tio.	

									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
200	2.4.5.6-	Tetraan	1513913421f	199 64891	8-0				reactions.
200		n iShoolpfaytein			(b)	Hair dye substatin oxidat hair dye produc	ets 3,4 %	(a) fter mixing under oxidative condition the Timaximu noixing nt rampplied	printed on tise label:
					, ,	dye substar in non- oxidat hair	(calcul ncæs sulpha	/ t \	ted

Status: Point in time view as at 31/01/2020.

		dye products	cause seulphate) 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 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
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

								_	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	√931841L_′	2 398 -995	Hair		After	To be
200		ypethyl)-	yzanyin 2	2200 000	dye			printed
	p-		nediami	ne	substan	ce	under	on the
		r Sadifanter			in		oxidativ	
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								Temporary 'black
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Status: Point in time view as at 31/01/2020.

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	diol					substa	nce	under	
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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	chloro-2 methylp	5- 4Amino- 2Chloro- benol 1Gredel HCl	-85-7	Hair dye substan in oxidativ hair dye product	ve	After mixing under oxidative conditions the maximum concent applied to hair must not exceed 1,5 % (calcular)	offshe mixing tractio.	Dons.

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Status: Point in time view as at 31/01/2020.

								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	J-Hair dye substan in oxidativ hair dye product	ve	After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 0,5 %	offshe mixing I na tio.	

							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. Hair colorants
								Hair
210	1H- Indole-2 Dione	Isatin 2,3-	91-56-5	202-077	7#&air dye substan in non- oxidativ		Read	7

Status: Point in time view as at 31/01/2020.

		hair dye product	S	follow instruction. This product is not intended for use on persons under the age of 16. Tempora 'black henna' tattoos may increase your	
		product	s	product is not intended for use on persons under the age of 16. Tempora 'black henna' tattoos may increase	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

211 2- 2- 16867-0240-886#8air After To	reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
Aminopyridine 3- ol Hydroxypyridine substance under on a oxidative condition.	nted the el:
dye maximu na ti	king o.
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Ten	nporary
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Status: Point in time view as at 31/01/2020.

								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. Hair colorants can cause severe allergic reactions.
212	2-	1-		24954-690			After	To be	
	naphthy acetate	-Acetoxy Methyli	y-2- naphthal	ene	dye substan in	ce	mixing under oxidativ	on the	

		oxidativ hair dye product	condition the maximum concent applied to hair must not exceed 2,0 % (When both 2-	mixing I na tio.	ons.
			the maximu concent on the head	ration's may increase your risk of	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.
213	2- yMethyl- Mapaphah	-1-	7 2 \$1-265	Hair dye substan in oxidativ hair dye product	ve	under oxidative condition the maximum concentrate applied to hair must not exceed 2,0 % (When both 2-Methyl-Naphth and 1-Acetoxy	Read and follow instruction product of intended	

Status: Point in time view as at 31/01/2020.

								colorants can cause severe allergic reactions.
214	Disodiu 5,7- dinitro- oxido-2 naphtha CI 10316	Yellow 81	2 12-690)-2 (a)	Hair dye substa in oxidat hair dye produc	ive	oxidative condition the Timeximum neixing and ratioplied	printed von otse label: um tration
				(b)	(H) Jair dye substa in non-oxidat hair dye product	ive	Hair colorants can cause severe allergic reactions Read and follow instruction. This product is not intended for use on persons under the age of 16. Tempora 'black henna' tattoos may increase your	S. Sons.

				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.'

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

240	4-	4-	99-56-9	202-766	5 ⊞ air		After	To be
	Nitro-1				dye		mixing	printed
	phenyle	nœdiami	ne		substan	ce	under	on the
		Phenyle	nediami	ne	in		oxidativ	/tabel:
					oxidativ	/e	condition	offshe
					hair		the	mixing
							maximu	ı na tio.

Status: Point in time view as at 31/01/2020.

	dye products	concentrapplied to hair must not exceed 0,5 % Hair colorants 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 your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged
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Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

weight any sou have ever experier any

(d) The entry with reference number 251 is replaced by the following:

251	2-(4-	HC	24905-	82 46-521	l H air	1,0 %		^
	Amino-				dye			/ \
	nitroan	il Mo)Tetha	anol		substan	ce		/ • \
					in			/ · \
					non-			nurosaung Hair agents
					oxidativ	/e		agents
					hair		_	coforants Maximum
					dye			can
					product	S		cause content:
								Sencie/
								reactions.
								Read
								and .
								affitrite- follow
								instructions.
								This
								product
								is not
								intended
								for
								use on
								persons
								under
								the

Status: Point in time view as at 31/01/2020.

							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 experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in
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(e) The entry with reference number 253 is replaced by the following:

253	2-	HC	59820-4	1328 -840) H air	1,5 %	 Do
	[bis(2-	Yellow			dye		not
	Hydrox	yNetthyll)a	mino]-5-		substan	ce	use
	nitroph	enol	_		in		with
	_				non-		nitrosating
					oxidativ	ve	agents
					hair		 Maximum
					dye		nitrosamine
					product	S	content:
					1		50 μg/
							kg
							 Keep
							in
							nitrite-
							free
							containers

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

255	2-[(2-	НС	4926-5	202 5-555	5-8				
		eYieyll)awn			(a)	Hair	(a)	(aA) fter	To
	r	No 2	- 1			dye		mixing	
		1102				substa	nce	under	printed
						in		oxidati	v e n
						oxidat	ive	condition	o tds e
						hair		the	label:
						dye		Tilmaximi	um
						produc	ets	ncioxinogn	
						Γ		rantpioplied	
					(b)	b l Hair	1,0 %		
					(0)	dye	1,0 /0	/\	
						substa	naa	/ı \	\
							lice	/ !	\
						in		exceed	_
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						oxidat	For (a)	and	
						hair	and	follow	
						dye		instruction	ons.
						produc	(180).	This	
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								is not uset	
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								for mitrosat	ina
								use on sau	ing
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							_	ınder	um ·
								under filtrosai the content	mine
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							heitnitė-	
							tafinens	
							ncaoyntain	ore
							increase	
							your	
							risk of	
							allergy.	
							Do not	
							colour	
							your	
							hair if:	
							nan n.	
							_	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
'	1	'	'	•	1	1	1	

								cause severe allergic reactio
256	4-[(2- Nitroph	HC (Dyd)ngu No 1	54381-(ino]pher	0 2 579-132 nol	dye substan in non- oxidativ hair dye product	⁄e		

ere ergic ctions.

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

258	2-	HC	2784-89	9 26 0-494		1,0 %	Λ	
	Nitro-	Red			dye		/_ \	
	N1-	No 1			substan	ce	/ 1	\
	phenyl-				in		/ •	\
	benzene	2 -1,4-			non-		D 1	_
	diamine				oxidativ	/e	Read	
					hair		and	
					dye		follow	
					product	S	instruction	ons.
					P	~	This	
							product	
							is not	
							intended	l
							for	
							use on	
							persons	
							under	
							the	
							age of	
							16.	
							Tempora	arv
							'black	,
							henna'	
							tattoos	
							may	
							increase	
							your	
							risk of	
							allergy.	
							Do not	
							colour	
							your	
							hair if:	
							11 a 11 11.	VOII
							_	you
								have
							İ	a

rash

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							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.
259	(β-	HC yygHow No 9 thyl)amin nzene, nloride	6 91 45-480	OHair dye substan- in non- oxidativ hair dye product	hydroch e	Do not use with nitrosat agents Maximu nitrosar content: 50 µg/kg	ing um nine

								Keep in nitrite- free containe	ers
260	1-(4'- Aminor methyl- (bis-2- hydroxy aminob	ethyl)	0)-2-	- 24 63420	dye substan in non- oxidativ hair dye product	⁄e			
261	N-(2- Hydrox nitro-4- trifluori aniline		10442-8	3348-760	(b)	Hair dye substatin oxidat hair dye substatin non-oxidat hair dye product	ets 2,5 % nce ive For (a) and	(a) fter mixing under oxidative condition the Tilmaximu ncioning entration of the tattops may be a see the tattop of the tattops may be a see the tattop of	printed onlse label: im ration ons.

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				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
					irritated and
				_	scalp, you
					ever experienced any reaction
					colouring your
				_	you have experienced
					a reaction to a
					temporary 'black henna' tattoo
					in the past.
					Hair colorants can
					cause severe allergic reactions.

262	Benzen	a Basiic ım	.68391-3	3 2 69-943	3 H5 air	2,0 %		
	3-	Yellow	,		dye	,		
	[(4,5-	57			substan	ce		
	dihydro	-3-			in			
	methyl-				non-			
	oxo-1-				oxidativ	/e		
	phenyl-	1H-			hair			
	pyrazol	-4-			dye			
	yl)azo].	1			product	s		
		rimethyl	- ,					
	chloride	•						
263	Ethanol	,Dispers	e20721-:	5 040 3-987	7 ₩ air	0,3 %		
	2,2'-	Black			dye	(of the		
	[[4-	9			substan	cenixture		
	[(4-				in	in the		
	aminop	henyl)az	opheny	l]imino]ˈ	omson-	ratio		
					oxidativ	/ d :1 of		
					hair	2,2'-		
					dye	[4-(4-		
					product		henylazo)phenylimino]diethanol
						and		
						lignosu	lfate)	
264	9,10-	НС	99788-7	7 \$ 1271-47() H air	lignosu 0,3 %	lfate) —	Do
264		HC		7 \$27 1-470	O H air dye	_	lfate) —	Do not
264	Anthrao	Bhledi on No 14		7 \$27 1-470		0,3 %	lfate) —	
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye	0,3 %	lfate)	not use with
264	Anthrac 1,4- bis[(2,3	Bhledi on No 14	e,		dye substan in non-	0,3 % ce	lfate)	not use
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in	0,3 % ce	Ifate)	not use with nitrosating agents
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair	0,3 % ce		not use with nitrosating agents Maximum
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair	0,3 % ce	Hfate)	not use with nitrosating agents Maximum nitrosamine content:
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce	Hfate)	not use with nitrosating agents Maximum nitrosamine content: 50 µg/
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents Maximum nitrosamine content: 50 µg/
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in nitrite-
264	Anthrac 1,4- bis[(2,3	Bhad ion No 14 -	e,		dye substan in non- oxidativ hair dye	0,3 % ce		not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in

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

Refere	n Se ubsta	ınce idei	ntificatio	on Restrictions				Wording
numbe	numberChemicaName name/ of INN Comn Ingred Glossa		numbe on lients	EC ernumbe	ProductMaxinertype, concerbody in parts ready use prepa		itration	of conditions of use and warnings
' 16	1- Naphth	1- a Neaph th		201-969	Hair dye		After mixing	To be printed

To be printed on the label: The mixing ratio.

Read and follow instruction This product is not intended for

									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	cced
									severe allergic reactions	
22	1,3- benzeno	Resorci ediol	nk08-46-	2 03-585	5-2 (a)	Hair dye substa in oxidat hair dye produc	2. ive For 1 and 2:	general use professi use	1. onal	To be print on the laber The mix ratio
					(b)	(b)air lotions and shamp	mixing under/ oxidative condition the maximum concent applied to hair must not exceed 1,25 %	ons ım ration		Rea and followinst This proof is not interfor

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

use on persons under the age of 16. Tempora 'black henna' tattoos may increase your risk of allergy. Do not colour your hair

if:

			2.

resorcino Rinse hair well after application Rinse eyes immedia if product comes into contact with them. Do not use to dye eyelashe eyebrows Hair colorants can cause severe allergic reactions To be printed on the label: The mixing ratio.

For professiouse only.

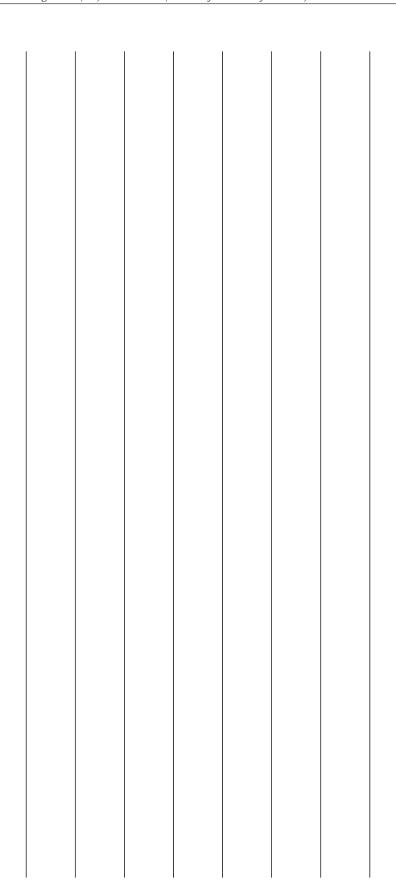
Contains

ANNEX

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Contains resorcing 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	
221	2-(4- Methyl- nitroan	Hydrox Nitro- ll m o)etha Toluidi	anol	- 30 85090)-7 (a)	Hair dye substa in oxidat hair	(a) fter mixing under oxidative condition the maximum	To be printed con othse label:	

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			dye		Tomencent	
			produc	ts	naippihied	
					r ati o.	
		(b)	(b Jair	1,0 %	^	
		(-)	dye		/_\	
			substa	nce	/ ! \	\
			in		/ :	\
			non-		Read Read	_
			oxidat	For (a)		
			hair	and	and	
			dye	(b):	follow	
			produc	` ′	instruction This	ons.
			produc		This	
					product	
					1371HH	
					intended	ing
					intended for agents	8
					use on Maximi	ım
					persons	nine
					persons infrosar under content	
					the µg/	•
					age of	
					165 Reen	
					Reep Tempora	ry
					'black nitrite-	
					henna'	
					tattoos	erc
					may	C13
					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. Hair colorants can cause severe allergic
250	1- HC Amino-Red nitro-4- No 10 (2',3'- + HC dihydroxRypdopy chlorobeNizehe + 1,4- bis- (2',3'- dihydroxypropy nitro-5- chlorobenzene	(a) (b)	dye substance in non- oxidative	mixin under oxidat condit the Timaxin ncixing rampolie (0 %)	reactions. To g be printed ivon ionise label: num ntration d its

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						agontaine	ers
						16.	213
						Tempora	rs.
						'black	ı y
						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
							experienced
							any
							reaction
							after
							colouring
							your
							hair,
							you
							have
							experienced
							a
							reaction
							to
l	l	I	I				

								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.

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Changes to legislation:

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