#### COMMISSION REGULATION (EU) No 1197/2013

#### of 25 November 2013

# 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:

- Following the publication of a scientific study in 2001, (1) 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 of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (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 mutagenicity.
- (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 of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision

2004/210/EC (3), assessed the safety of individual 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.
- (6) In order to ensure the safety of hair dye products for human health it is appropriate to limit the maximum concentrations of 21 assessed hair dye substances and to list them in Annex III to Regulation (EC) No 1223/2009, by taking into account the final opinions given by the SCCS on their safety.
- (7) Following the assessment by the SCCS concerning the substance Toluene-2,5-Diamine, listed in entry 9a of Annex III to Regulation (EC) No 1223/2009, it is appropriate to change the maximum authorised concentrations thereof in the finished cosmetic product.
- (8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded its application on eyelashes. This 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.
- The SCCS, in its opinion on oxidative hair dye substances (9) and hydrogen peroxide used in products to colour eyelashes of 12 October 2012, concluded that oxidative hair dye substances p-Phenylenediamine, Resorcinol, 6-Methoxy-2-Methylamino-3-Aminopyridine HCl, m-Aminophenol, 2-Methyl-5-Hydroxyethyl Aminophenol, 4-Amino-2-Hydroxytoluene, 2,4-Diaminophenoxyethanol HCl, 4-Amino-m-Cresol, 2-Amino-4-Hydroxyethylaminoanisole and 2,6-Diaminopyridine, 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. In addition, the SCCS concluded that up to 2 % of hydrogen peroxide, which is listed under entry 12 in Annex III to Regulation (EC) No 1223/2009, can be considered safe for consumers when applied on eyelashes.

<sup>(1)</sup> OJ L 342, 22.12.2009, p. 59.

<sup>(2)</sup> OJ L 66, 4.3.2004, p. 45.

<sup>(3)</sup> OJ L 241, 10.9.2008, p. 21.

- (10) On the basis of the scientific assessment of those substances their use should be allowed in products intended for colouring eyelashes in the same concentrations as in hair dye products. 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 eyelash colouring 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) In order to avoid a disruption on the market due to the transition from Council Directive 76/768/ECC of 27 July 1976 on cosmetic products (¹) to Regulation (EC) No 1223/2009, this Regulation should apply from the same date as Regulation (EC) No 1223/2009.
- (13) A sufficient transition period should be granted to economic operators in order to comply with the new warnings for products intended for colouring eyelashes.

(14) 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 day following that of its publication in the Official Journal of the European Union.

It shall apply from 11 July 2013.

However, the following provisions in the Annex shall apply from 1 July 2014:

- (a) the provisions in column 'i' of point 1 and of points 3 to 9 relating to the use of the substances in products intended for colouring eyelashes;
- (b) points 2 and 10.

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

Done at Brussels, 25 November 2013.

For the Commission
The President
José Manuel BARROSO

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

(1) the following entry 8b is inserted:

a	ь	С	d	e	f	g	h	i
*8b	p-Phenylene-diamine and its salts	p-Phenylenediamine; p-Phenylenediamine HCl; p-Phenylenediamine Sulphate	106-50-3   624-18-0   16245-77-5	203-404-7   210-834-9   240-357-1	Products intended for colouring eyelashes		After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 2 % calculated as free base  For professional use only.	To be printed on the label:  The mixing ratio.  "For professional use only.  This product can cause severe allergic reactions.  Read and follow instructions.  This product is not intended for use opersons under the age of 16.  Temporary 'black henna' tattoos may increase the risk of allergy.  Eyelashes shall not be coloured if the consumer:  — has a rash on the face or sensitive irritated and damaged scalp,  — has experienced any reaction after colouring hair or eyelashes,  — has experienced a reaction to a temporary 'black henna' tattoo in the past.  Rinse eyes immediately if product comes into contact with them.  Contains phenylenediamines.  Wear suitable gloves."

ANNEX

## (2) entry 9a is replaced by the following:

a	ь	с	d	e	f	g	h	i
·9a)	1,4-Benzene-diamine, 2-methyl- 2,5-Diamino-toluene sulphate	Toluene-2,5-Diamine Toluene-2,5-Diamine sulfate (¹)	95-70-5 615-50-9	202-442-1 210-431-8	Hair dye substance in oxidative hair dye products		(b) Professional use  For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % (calculated as free base) or 3,6 % (calculated as sulfate salt)	<ul> <li>(a) To be printed on the label:             The mixing ratio.             " 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 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.                   Contains phenylenediamines (toluenediamines).                   Do not use to dye eyelashes or eyebrows."</li></ul>

	1
may increa  Do not co  — you ha  or sens  damage  — you ha  reaction  hair,  — you ha  reaction  henna'  Contains p  (toluenedia	y 'black henna' tattoos case your risk of allergy. blour your hair if: ave a rash on your face sitive, irritated and ged scalp, ave ever experienced any on after colouring your ave experienced a on to a temporary 'black' tattoo in the past. phenylenediamines amines). able gloves."

## (3) entry 12 is replaced by the following:

a	ь	С	d	e	f	g	h	i
'12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide	Hydrogen peroxide	7722-84-1	231-765-0	(a) Hair products  (b) Skin products	(a) 12 % of H <sub>2</sub> O <sub>2</sub> (40 volumes), present or released  (b) 4 % of H <sub>2</sub> O <sub>2</sub> ,		For (a) and (f): Wear suitable gloves  For (a) (b) (c) and (e):  Contains hydrogen peroxide.  Avoid contact with eyes.
	peroxide and zinc peroxide				(c) Nail hardening products	present or released  (c) 2 % of H <sub>2</sub> O <sub>2</sub> , present or released		Rinse immediately if product comes into contact with them.
					(d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products	(d) $\leq 0.1$ % of $H_2O_2$ , present or released		

315/39

a	ь	С	d	e	f	g	h	i
					(e) Tooth whitening or bleaching products	(e) $> 0.1 \%$ $\le 6 \% \text{ of}$ $H_2O_2$ ,	(e) To be only sold to dental practitioners.	(e) Concentration of H <sub>2</sub> O <sub>2</sub> present or released indicated in percentage.
						present or released	For each cycle of use, first use by dental practi- tioners as defined under	Not to be used on a person under 18 years of age.
							Directive 2005/36/EC (5) or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.	To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.
							Not to be used on a person under 18 years of age.	
					(f) Products intended for	(f) 2 % of H <sub>2</sub> O <sub>2</sub> ,	(f) For professional use only	(f) To be printed on the label:
					eyelashes	present or released		"For professional use only.
								Avoid contact with eyes.
								Rinse eyes immediately if product comes into contact with them.
								Contains hydrogen peroxide."
(=)	255 200 2005							

<sup>(5)</sup> OJ L 255, 30.9.2005, p. 22.'

## (4) entry 22 is replaced by the following:

a	Ъ	с	d	e	f	g	h	i
'22	1,3-benzenediol	Resorcinol	108-46-3	203-585-2	(a) Hair dye substance in		For (a) and (b):	(a) To be printed on the label:
					oxidative hair dye products		After mixing under oxidative conditions the maximum	The mixing ratio.
							concentration applied to hair or eyelashes must not exceed 1,25 %	"/t Hair colorants can cause severe allergic reactions.

a	ь	с	d	e	f	g	h	i
								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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past.  Contains resorcinol.  Rinse hair well after application.  Rinse eyes immediately if product comes into contact with them.  Do not use to dye eyelashes or eyebrows."
					(b) Products intended for colouring eyelashes		(b) For professional use only.	(b) To be printed on the label:  The mixing ratio.  "For professional use only.  Contains resorcinol.  This product can cause severe allergic reactions.  Read and follow instructions.

a	ь	с	d	e	f	g	h	i
								This product is not intended for use on persons under the age of 16.
								Temporary 'black henna' tattoos may increase the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."
					(c) Hair lotions and shampoos	(c) 0,5 %		(c) Contains resorcinol.'

## (5) entry 203 is replaced by the following:

a	ь	с	d	e	f	g	h	i
'203	6-Methoxy-N2- methyl-2,3-pyri- dinediamine hydrochloride and dihydrochloride salt ( <sup>17</sup> )	6-Methoxy-2-Methyl- amino-3-Amin- opyridine HCl	90817-34-8   83732-72-3	-   280-622-9	(a) Hair dye substance in oxidative hair dye products		For (a) and (c): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 0,68 % calculated as free base (1,0 % as dihydrochloride).	(a) To be printed on the label:  The mixing ratio.  "A 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.

a	ь	С	d	e	f	g	h	i
					(b) Hair dye substance in non-oxidative hair dye products	(b) 0,68 % as free base (1,0 % as dihydrochloride)	For (a) (b) and (c):  — Do not use with nitrosating agents  — Maximum nitrosamine content: 50 μg /kg  — Keep in nitrite-free containers	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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."  (b) Can cause allergic reaction
					(c) Products intended for colouring eyelashes		(c) For professional use only.	(c) To be printed on the label:  The mixing ratio.  "For professional use only.  This product can cause severe allergic reactions.  Read and follow instructions.  This product is not intended for use on persons under the age of 16.

a	ь	с	d	e	f	g	h	i
								Temporary 'black henna' tattoos may increase the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								has experienced a reaction to a temporary 'black henna' tattoo in the past.
								Rinse eyes immediately if product comes into contact with them."

## (6) entry 217 is replaced by the following:

a	Ъ	с	d	e	f	g	h	i
·217	m-Aminophenol and its salts	m-Aminophenol m-Aminophenol HCl m-Aminophenol sulfate	591-27-5   51-81-0   68239-81-6  38171-54-9	209-711-2   200-125-2   269-475-1	(a) Hair dye substance in oxidative hair dye products		For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,2 %	(a) To be printed on the label:  The mixing ratio.  "A 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.

a b	с	d	e	f	g	h	i
							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."
				(b) Products intended for colouring eyelashes		(b) For professional use only.	<ul> <li>(b) To be printed on the label:  The mixing ratio.  "For professional use only.  This product 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 the risk of allergy.  Eyelashes shall not be coloured if the consumer:  has a rash on the face or sensitive, irritated and damaged scalp,  has experienced any reaction after colouring hair or eyelashes,</li> </ul>

a	ь	С	d	e	f	g	h	i
								has experienced a reaction to a temporary 'black henna' tattoo in the past.
								Rinse eyes immediately if product comes into contact with them."
ntry :	229 is replaced by t	the following:						
a	ь	С	d	e	f	g	h	i
2229	5-[(2-Hydroxye-thyl)amino]-o-cresol	2-Methyl-5-Hydro- xyethyl Aminophenol	55302-96-0	259-583-7	(a) Hair dye substance in oxidative hair dye products		For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 %  — Do not use with nitrosating agents  — Maximum nitrosamine content: 50 µg /kg  — Keep in nitrite-free containers	(a) To be printed on the label:  The mixing ratio.  "A 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 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."
					(b) Products intended for colouring eyelashes		(b) For professional use only.	(b) To be printed on the label:  The mixing ratio.

a	Ъ	с	d	e	f	g	h	i
								"For professional use only.
								This product 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 the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								— has a rash on the face or sensitive, irritated and damaged scalp,
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								has experienced a reaction to a temporary 'black henna' tattoo in the past.
								Rinse eyes immediately if product comes into contact with them."

(8) entries 241 and 242 are replaced by the following:

a	ь	С	d	e	f	g	h	i
<b>'241</b>	5-Amino-o-cresol	4-Amino-2-Hydroxy- toluene	2835-95-2	220-618-6	(a) Hair dye substance in oxidative hair dye products		For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 %	(a) To be printed on the label:  The mixing ratio.  "A Hair colorants can cause severe allergic reactions.

a	ь	с	d	e	f	g	h	i	26.1
								Read and follow instructions.	26.11.2013
								This product is not intended for use on persons under the age of 16.	
								Temporary 'black henna' tattoos may increase your risk of allergy.	EN
								Do not colour your hair if:	
								<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>	
								<ul> <li>you have ever experienced any reaction after colouring your hair,</li> </ul>	Official
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."	Official Journal of the European Union
					(b) Products intended for		(b) For professional use only.	(b) To be printed on the label:	he Eui
					colouring eyelashes			The mixing ratio.	opear
								"For professional use only.	1 Unic
								This product can cause severe allergic reactions.	ň
								Read and follow instructions.	
								This product is not intended for use on persons under the age of 16.	
								Temporary 'black henna' tattoos may increase the risk of allergy.	
								Eyelashes shall not be coloured if the consumer:	
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>	315/47

a	ь	с	d	e	f	g	h	i
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."
12	2,4-Diaminophen- oxyethanol, its	2,4-Diaminophenoxy- ethanol HCl	70643-19-5/ 66422-95-5/	-	(a) Hair dye substance in		For (a) and (b): After mixing under oxidative conditions the	(a) To be printed on the label:
	hydrochloride and its sulphate	2,4-Diaminophenoxy-	70643-20-8	7 27 17 13 2	oxidative hair dye products		maximum concentration applied to hair or eyelashes	The mixing ratio.
	•	ethanol sulfate					must not exceed 2,0 % (as hydrochloride)	"A 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:
								<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>
								you have ever experienced any reaction after colouring your hair,
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."
					(b) Products intended for		(b) For professional use only.	(b) To be printed on the label:
					colouring eyelashes			The mixing ratio.

a	ь	с	d	e	f	g	h	i
								"For professional use only.
								This product 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 the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."

(9) entries 244 and 245 are replaced by the following:

a	ь	с	d	e	f	g	h	i
<b>'244</b>	4-Amino-m-cresol	4-Amino-m-Cresol	2835-99-6	220-621-2	(a) Hair dye substance in oxidative hair dye products		For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 %	(a) To be printed on the label:  The mixing ratio.  "A Hair colorants can cause severe allergic reactions.

a	ь	С	d	e	f	g	h	i
a	b	c	d	e	f	g	h	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 your hair,
					(b) Products intended for colouring eyelashes		(b) For professional use only.	<ul> <li>— you have experienced a reaction to a temporary 'black henna' tattoo in the past."</li> <li>(b) To be printed on the label:  The mixing ratio.  "For professional use only.  This product can cause severe allergic reactions.</li> </ul>
								Read and follow instructions.  This product is not intended for use on persons under the age of 16.  Temporary 'black henna' tattoos may increase the risk of allergy.  Eyelashes shall not be coloured if the consumer:  — has a rash on the face or sensitive, irritated and damaged scalp,

EN

Official Journal of the European Union

26.11.2013

a	ь	с	d	e	f	g	h	i
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."
245	2-[(3amino-4- methoxyphenyl)	2-Amino-4-Hydroxye- thylaminoanisole	83763-47-7	280-733-2 /	(a) Hair dye substance in		For (a) and (b): After mixing under oxidative conditions the	(a) To be printed on the label:
	amino]ethanol and its sulphate	2-Amino-4-Hydroxye-	83763-48-8	280-734-8	oxidative hair dye products		maximum concentration applied to hair or eyelashes	The mixing ratio.
		thylaminoanisole sulfate					must not exceed 1,5 % (as sulphate)	"  Hair colorants can cause severe allergic reactions.
							Do not use with nitrosating agents	Read and follow instructions.
							— Maximum nitrosamine content: 50 μg /kg	This product is not intended for use on persons under the age of 16.
							Keep in nitrite-free containers	Temporary 'black henna' tattoos may increase your risk of allergy.
								Do not colour your hair if:
								<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>you have ever experienced any reaction after colouring your hair,</li> </ul>
								<ul> <li>you have experienced a reaction to a temporary 'black henna' tattoo in the past."</li> </ul>
					(b) Products intended for		(b) For professional use only.	(b) To be printed on the label:
					colouring eyelashes			The mixing ratio.

a	Ъ	с	d	e	f	g	h	i
								"For professional use only.
								This product 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 the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."

## (10) the following entries 265 to 285 are added:

a	Ъ	с	d	e	f	g	h	i
'265	1,4-Diaminoan- thraquinone	Disperse Violet 1	128-95-0	204-922-6	Hair dye substance in non-oxidative hair dye products	0,5 %	Impurity of Disperse Red 15 in Disperse Violet 1 for hair dye formulations should be < 1 % (w/w)	
266	Ethanol, 2-((4- amino-2-nitrophe- nyl)amino)-	HC Red No 3	2871-01-4	220-701-7	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,45 %	For (a): To be printed on the label:  The mixing ratio.

a	ь	С	d	e	f	g	h	i	26.1
					(b) Hair dye substance in non-oxidative hair dye products	(b) 3,0 %	For (a) and (b):  — Do not use with nitrosating agents  — Maximum nitrosamine content: 50 µg/kg  — Keep in nitrite-free containers	For (a) and (b):  "Alair 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 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."	26.11.2013 EN Official Journal of the European Union
267	[7-Hydroxy-8-[(2-methoxyphe-nyl)azo]-2-naph-thyl]trimethyl-ammonium chloride	Basic Red 76	68391-30-0	269-941-4	Hair dye substance in non-oxidative hair dye products	2,0 %			pean Union
268	2-[[4-(Dimethyl- amino)phe- nyl]azo]-1,3- dimethyl-1H-imid- azolium chloride	Basic Red 51	77061-58-6	278-601-4	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	(a) To be printed on the label:  The mixing ratio.  "A 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.	L 315/53

a	Ъ	С	d	e	f	g	h	i
					(b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %		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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."
Phenol, 5-Ethyl-, chloride	2-Amino-, Hydro-	2-Amino-5- Ethylphenol HCl	149861-22-3		Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	To be printed on the label:  The mixing ratio.  "A 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 scalp,  — you have ever experienced any reaction after colouring your hair,

a	ь	С	d	e	f	g	h	i
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."
270	Fluorescein, 2',4',5',7'-tetra- bromo-4,5,6,7- tetrachloro-, disodium salt (CI 45410)	Acid Red 92	18472-87-2	242-355-6	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 0,4 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 %	<ul> <li>(a) To be printed on the label:  The mixing ratio.  "A 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 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."</li> </ul>
271	Mixture of (1), (2) & (3) in dispersing agent (lignosulphate):	Disperse Blue 377 is a mixture of three dyes:			Hair dye substance in non-oxidative hair dye products	2,0 %		
	(1) 9,10-Anthracenedione- 1,4-bis[(2- Hydroxye- thyl)amino]	(1) 1,4-bis[(2-hydro- xyethyl)amino]an- thra-9,10-quinone	(1) 4471-41-	(1) 224-743-				

a	ь	С	d	e	f	g	h	i	L 31
	(2) 9,10-Anthracenedione-1- [(2-Hydroxyethyl)amino]- 4-[(3- Hydroxypropyl)amino]	(2) 1-[(2-hydroxye- thyl)amino]-4-[(3- hydroxypro- pyl)amino]anthra- 9,10-quinone	(2) 67674- 26-4	(2) 266-865-					315/56 EN
	(3) 9,10-anthracenedione- 1,4-bis[(3-hydroxypro- pyl)amino	(3) 1,4-bis[(3- hydroxypro- pyl)amino]anthra- 9,10-quinone	(3) 67701- 36-4	(3) 266-954- 7					
272	4-Aminophenol	p-Aminophenol	123-30-8	204-616-2	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,9 %	To be printed on the label:  The mixing ratio.  "A 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 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."	Official Journal of the European Union
273	4,5-Diamino-1-(2-hydroxyethyl)-1H-pyrazole sulfate (1:1)	1-Hydroxyethyl-4,5- Diamino Pyrazole Sulfate	155601-30-2	429-300-3	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,0 %	To be printed on the label: The mixing ratio.	26.11.2013

a	ь	С	d	e	f	g	h	i
								"/! 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 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."
274	Quinolinium, 4- formyl-1-methyl-,	4-Formyl-1-Methylqui- nolinium-p-Toluene-	223398-02-5	453-790-8	Hair dye substance in oxidative hair dye		After mixing under oxidative conditions the maximum	To be printed on the label:
	salt with 4- methylbenzene-	sulfonate			products		concentration applied to hair must not exceed 2,5 %	The mixing ratio.
	sulfonic acid (1:1)							"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:
								<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>
								sensitive, irritated and da

26.11.2013

EN

Official Journal of the European Union

L 315/57

a	ь	С	d	e	f	g	h	i	L 31
								you have ever experienced any reaction after colouring your hair,	315/58
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."	EN
275	Pyridinium, 1- methyl-4-[(	Basic Yellow 87	68259-00-7	269-503-2	(a) Hair dye substance in		(a) After mixing under oxidative conditions the	(a) To be printed on the label:	
	methylphenylhy- drazono)methyl]-,				oxidative hair dye products		maximum concentration applied to hair must not	The mixing ratio.	
	methyl sulfate						exceed 1,0 %	"     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.	Official Jour
								Temporary 'black henna' tattoos may increase your risk of allergy.	nal of the
								Do not colour your hair if:	e Euro
								<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>	Official Journal of the European Union
								you have ever experienced any reaction after colouring your hair,	
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."	
					(b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %			
276	2-[(4-Aminophenyl)azo]-1,3- dimethyl-1H-imid- azolium chloride	Basic Orange 31	97404-02-9	306-764-4	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	(a) To be printed on the label:  The mixing ratio.	26.11.2013

a	ь	С	d	e	f	g	h	i	26.1
								"A Hair colorants can cause severe allergic reactions.  Read and follow instructions.  This product is not intended for use on persons under the age	26.11.2013 EN
					(b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %		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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."	Official Journal of the European Union
277	2,6-Pyridine- diamine, 3-(3- pyridinylazo)	2,6-Diamino-3- ((Pyridine-3-yl)azo)Py- ridine	28365-08-4	421-430-9	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 %	(a) To be printed on the label:  The mixing ratio.  "A 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.	L 315/59

a	ь	С	d	e	f	g	h	i	
					(b) Hair dye substance in non-oxidative hair dye products	(b) 0,25 %		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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."	OTTOM JOHITH
278	4-((4-Amino-3-methylphenyl)(4-imino-3-methyl-2,5-cyclohex-adien-1-ylidene)methyl)-2-methylpheny-lamine monohydrochloride (CI 42520)	Basic Violet 2	3248-91-7	221-831-7	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	(a) To be printed on the label:  The mixing ratio.  "A 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 scalp,	CITIENT JOHNS OF THE THE CHARLESTEE

a	ь	С	đ	e	f	g	h	i	26.1
					(b) Hair dye substance in non-oxidative hair dye products	(b) 0,5 %		— you have ever experienced any reaction after colouring your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."	26.11.2013 EN
279	2,3-Diamino-6,7-dihydro-1H,5H-pyrazolo[1,2-a] Pyrazol-1-one dimethanesul-fonate	2,3-Diaminodihy-dropyrazolopyrazolopyrazolopine Dimethosulfonate	857035-95-1	469-500-8	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 %	To be printed on the label:  The mixing ratio.  "Alair 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 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."	Official Journal of the European Union
280	2-Amino-4,6-dini- trophenol and 2- amino-4,6-dinitro- phenol, sodium salt	Picramic Acid and Sodium Picramate	96-91-3 831-52-7	202-544-6 212-603-8	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,6 %	(a) To be printed on the label:  The mixing ratio.	L 315/61

a	ь	С	d	e	f	g	h	i	L 31
					(b) Hair dye substance in non-oxidative hair dye products	(b) 0,6 %		"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 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."	315/62 EN Official Journal of the European Union
281	1-Methylamino-2- nitro-5-(2,3-dihy- droxy-propyloxy)- benzene	2-Nitro-5-Glyceryl Methylaniline	80062-31-3	279-383-3	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,8 %	(a) To be printed on the label:  The mixing ratio.  "A 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.	26.11.2013

a	ь	с	d	e	f	g	h	i
					(b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %	For (a) and (b):  — Do not use with nitrosating agents  — Maximum nitrosamine content: 50 µg/kg  — Keep in nitrite-free containers	Temporary 'black henna' tattoos may increase your risk of allergy  Do not colour your hair if:  — you have a rash on your factor sensitive, irritated and damaged scalp,  — you have ever experienced an reaction after colouring your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."
282	1-Propanaminium, 3-[[9,10-dihydro- 4-(methylamino)- 9,10-dioxo-1- anthracenyl] amino]-N,N- dimethyl-N- propyl-, bromide	HC Blue 16	502453-61-4	481-170-7	Hair dye substance in non-oxidative hair dye products	3,0 %	<ul> <li>Do not use with nitrosating agents</li> <li>Maximum nitrosamine content: 50 μg/kg</li> <li>Keep in nitrite-free containers</li> </ul>	
283	3-amino-2-chlor- 6-methylphenol 3-amino-4-chloro- 6-methylphenol HCl	5-Amino-6-Chloro-o- Cresol 5-Amino-6-Chloro-o- Cresol HCl	84540-50-1 80419-48-3	283-144-9	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	(a) To be printed on the label:  The mixing ratio.  "A Hair colorants can cause severe allergic reactions.  Read and follow instructions.

a	b	С	d	e	f	g	h	i
					(b) Hair dye substance in non-oxidative hair dye products	(b) 0,5 %		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 your hair,  — you have experienced a reaction to a temporary 'black henna' tattoo in the past."
284	Phenol, 2,2'- methylenebis[4- amino-], dihydro- chloride	2,2'-Methylenebis-4- aminophenol HCl	27311-52-0 63969-46-0	440-850-3	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	(a) To be printed on the label:  The mixing ratio.  "A 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.

Official Journal of the European Union

26.11.2013

a	ь	С	d	e	f	g	h	i
					(b) Hair dye substance in non-oxidative	(b) 1,0 %		<ul> <li>Do not colour your hair if:</li> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> <li>you have ever experienced any reaction after colouring your hair,</li> <li>you have experienced a reaction to a temporary 'black henna' tattoo in the past."</li> </ul>
285	Pyridine-2,6-diyldiamine	2,6-Diaminopyridine	141-86-6	205-507-2	(a) Hair dye substance in oxidative hair dye products		For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,15 %	(a) To be printed on the label:  The mixing ratio.  "A 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 scalp,  — you have ever experienced any reaction after colouring your

a	ь	С	d	e	f	g	h	i
								you have experienced a reaction to a temporary 'black henna' tattoo in the past."
					(b) Products intended for		(b) For professional use only.	(b) To be printed on the label:
					colouring eyelashes			The mixing ratio.
								"For professional use only.
								This product 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 the risk of allergy.
								Eyelashes shall not be coloured if the consumer:
								<ul> <li>has a rash on the face or sensitive, irritated and damaged scalp,</li> </ul>
								<ul> <li>has experienced any reaction after colouring hair or eyelashes,</li> </ul>
								<ul> <li>has experienced a reaction to a temporary 'black henna' tattoo in the past.</li> </ul>
								Rinse eyes immediately if product comes into contact with them."