



Brussels, **XXX**
[...](2016) **XXX** draft

ANNEX 1

ANNEX

to the


Commission Regulation (EU) .../...

**amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and
of the Council on cosmetic products**


ANNEX

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


(1) The following entry is added as reference number 8c:

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
'8c	Ethanol, 2,2'-[(2-nitro-1,4-phenylene)diimino]bis-(9CI)	N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine	84041-77-0	281-856-4	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5% For (a) and (b): - 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.  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."



(2) the text in entry 9, column b, is replaced by the following:


							<p>(calculated as free base) or 3,6 % (calculated as sulfate salt)</p>	<p>Do not use to dye eyelashes or eyebrows.'</p> <p>(a) (ii) (b) Wear suitable gloves. For professional use only.</p> <p>(a) (b) Contains phenylenediamines (toluenediamines).</p> <p>(b)  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:</p> <ul style="list-style-type: none"> - 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. <p>Rinse eyes immediately if product comes into contact with them.'</p>
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(4) the following entry is added as a reference number 9b:


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
'9b	1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene	2,6-Dihydroxyethylaminotoluene	149330-25-6	443-210-1	Hair dye substance in oxidative hair dye products		<p>After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0%</p> <ul style="list-style-type: none"> - Do not use with nitrosating agents - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers 	<p>To be printed on the label: The mixing ratio.</p> <p> 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.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - 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."



(5) the entries 200, 206, 211, 243 and 272 are 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
200	2,4,5,6-Tetraaminopyrimidine sulphate	Tetraaminopyrimidine Sulfate	5392-28-9	226-393-0	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products (c) Products intended for colouring eyelashes	(b) 3,4 % (calculated as sulfate)	(a) (c) After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 3,4 % (calculated as sulfate) (c) Professional use	(a) (c) 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.' (c) '  This product can cause severe allergic


								<p>reactions. Read and follow instructions.</p> <p>This product is not intended for use on persons under the age of 16. Temporary "black henna" tattoos may increase the risk of allergy.</p> <p>Eyelashes shall not be coloured if the consumer:</p> <ul style="list-style-type: none"> - 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. <p>For professional use only.</p> <p>Rinse eyes immediately if product comes into contact with them.'</p>
206	3-(2-Hydroxyethyl)- p-phenylenediammonium sulphate	Hydroxyethyl-p-Phenylenediamine Sulfate	93841-25-9	298-995-1	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Products intended for colouring eyelashes</p>		<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (calculated as sulphate)</p> <p>(b) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 1,75%</p> <p>(b) Professional use</p>	<p>(a) (b) To be printed on the label: The mixing ratio.</p> <p>(a) '  Hair colorants can cause severe allergic reactions.</p> <p>Read and follow instructions.</p> <p>This product is not intended for use on persons under the age of 16.</p> <p>Temporary "black henna" tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - you have a rash on your face or sensitive, irritated and

								<p>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.'</p> <p>(b) '  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, - has experienced a reaction to a temporary "black henna" tattoo in the past.</p> <p>For professional use only.</p> <p>Rinse eyes immediately if product comes into contact with them.'</p>
211	2-Aminopyridin-3-ol	2-Amino-3-Hydroxypyridine	16867-03-1	240-886-8	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	<p>(a) (b) To be printed on the label: The mixing ratio.</p> <p>(a) '  Hair colorants can cause severe allergic reactions.</p>

					<p>(b) Products intended for colouring eyelashes</p>	<p>(b) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 0,5 %</p> <p>(b) Professional use</p>	<p>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.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - 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.' <p>(b) '  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:</p> <ul style="list-style-type: none"> - 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.
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								For professional use only. Rinse eyes immediately if product comes into contact with them.'
243	1,3-benzenediol, 2-methyl	2-Methylresorcinol	608-25-3	210-155-8	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products (c) Products intended for colouring eyelashes	(b) 1,8 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,8 % (c) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 1.25% (c) Professional use	(a) (c) 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.' (c) '  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.



								<p>Eyelashes shall not be coloured if the consumer:</p> <ul style="list-style-type: none"> - 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. <p>For professional use only.</p> <p>Rinse eyes immediately if product comes into contact with them.'</p>
272	4-Aminophenol	p-Aminophenol	123-30-8	204-616-2	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Products intended for colouring eyelashes</p>		<p>(a) (b) After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 0,9 %</p> <p>(b) Professional use</p>	<p>(a) (b) To be printed on the label: The mixing ratio.</p> <p>(a) '  Hair colorants can cause severe allergic reactions.</p> <p>Read and follow instructions. This product is not intended for use on persons under the age of 16.</p> <p>Temporary "black henna" tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - 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.'


								<p>(b) '  This product can cause severe allergic reactions. Read and follow instructions.</p> <p>This product is not intended for use on persons under the age of 16. Temporary "black henna" tattoos may increase the risk of allergy.</p> <p>Eyelashes shall not be coloured if the consumer:</p> <ul style="list-style-type: none"> - 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. <p>For professional use only.</p> <p>Rinse eyes immediately if product comes into contact with them.'</p>
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(6) the following entries 289 to 296 are added:

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

289	Di-[2-[4-[(E)-2-[4-[bis(2-hydroxyethyl)aminophenyl]vinyl]pyridin-1-ium]butanoyl]aminoethyl]disulfanyl dichloride	HC Red No. 17	1449471-67-3		Hair dye substance in non-oxidative hair dye products	0.5%	- Do not use with nitrosating agents - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	
290	Di-[2-[4-[(E)-2-[2,4,5-trimethoxyphenyl]vinyl]pyridin-1-ium]butanoyl]aminoethyl]disulfanyl dichloride	HC Yellow No. 17	1450801-55-4		Hair dye substance in non-oxidative hair dye products	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 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.'
291	1H-Pyrazole-4,5-diamine, 1-hexyl-, sulfate (2:1)	1-Hexyl 4,5-diamino pyrazole sulfate	1361000-03-4		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. '  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.'
292	4-Hydroxy-2,5,6-triaminopyrimidine sulfate	2,5,6-Triamino-4-pyrimidinol sulfate	1603-02-7	216-500-9	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5%	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.'
293	2-[(3-aminopyrazolo[1,5-a]pyridin-2-yl)oxy]ethanol hydrochloride	Hydroxyethoxy aminopyrazolopyridine HCl	1079221-49-0	695-745-7	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. '  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.'
294	Phenol, 3-amino-2,6-dimethyl	3-amino-2,6-dimethylphenol	6994-64-5	230-268-6	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. '  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.'
295	2-Naphthalenaminium, 8-[(4-amino-3-nitrophenyl)azo]-7-hydroxy-N,N,N-trimethyl-, chloride	Basic Brown 17	68391-32-2	269-944-0	Hair dye substance in non-oxidative hair dye products	2.0%		

296	3-Amino-7-(dimethylamino)-2-methoxyphenoxazin-5-ium chloride	Basic Blue 124	67846-56-4	267-370-5	Hair dye substance in non-oxidative hair dye products	0.5%	<ul style="list-style-type: none"> - Do not use with nitrosating agents - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers 	<p> 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.</p> <p>Temporary "black henna" tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - 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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