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From: European Commission  
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Subject: 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

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Delegations will find attached document D047413/01 ANNEX 1.

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Encl.: D047413/01 ANNEX 1



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**

DO47413/01

**ANNEX**

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

(1) The following entry is inserted 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  |   |   |
| 8c               | a   | b   | c          | d         | e  | f  | g  | h   | i |
|                  | 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<br><br>(b) Hair dye substance in non-oxidative hair dye products | (b) As from [date = 6 months after the date of entry into force of this Regulation]: 1,5 % | For (a) and (b), as from [date = 6 months after the date of entry into force of this Regulation]:<br>- Do not use with nitrosating agents<br>- Maximum nitrosamine content: 50 µg/kg | (a) As from [date = 6 months after the date of entry into force of this Regulation], to be printed on the label:<br>The mixing ratio.<br><br>⚠ Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring |   |

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|  |  |  |  |  |  |  |  |  | - Keep in nitrite-free containers | your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past." |
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(2) the text in entry 9, column b, is replaced by the following:

‘Methylphenylenediamines, their N-substituted derivatives and their salts<sup>(1)</sup> with the exception of the substances under reference numbers 9a and 9b of this Annex and substances under reference numbers 364, 1310 and 1313 in Annex II’;

(3) the entry 9a is replaced by the following:


| Reference number | Substance identification                                 |   |                     |                        | Restrictions   |   |  | Wordings of conditions of use and warnings |
|------------------|--|---|---------------------|------------------------|--|---|--|--|
|                  | Chemical name/INN  | Name of Common Ingredients Glossary                               | CAS number          | EC number              | Product type, body parts   | Maximum concentration in ready use preparation          | Other  |  |
| a                | b  | c   | d                   | e                      | f  | g   | h  | i  |
| 9a               | 1,4-Benzenediamine, 2-methyl-2,5-Diaminotoluene sulphate | Toluene-2,5-Diamine<br>Toluene-2,5-Diamine Sulfate <sup>(1)</sup> | 95-70-5<br>615-50-9 | 202-442-1<br>210-431-8 | (a) Hair dye substance in oxidative hair dye products<br><br>(b) Products intended for | (a)<br><br>(i) General use<br><br>(ii) Professional use | (a) To be printed on the label:<br>The mixing ratio.<br><br>⚠ 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.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced |  |








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|  |  |  |  |  |  |  |  |  | containers | - you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past." |
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(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<br>(b) Hair dye substance in non-oxidative hair dye products<br>(c) Products intended for colouring | (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)<br>(c) Professional use | (a) To be printed on the label: The mixing ratio.<br> 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: |  |


|  |  |  |  |  |           |  |   |
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|  |  |  |  |  | eyelashes |  | <p>- you have a rash on your face or sensitive, irritated and damaged scalp,<br/> - you have ever experienced any reaction after colouring your hair,<br/> - you have experienced a reaction to a temporary "black henna" tattoo in the past.'</p> <p>(c) As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label: The mixing ratio.</p> <p> 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:<br/> - has a rash on the face or sensitive, irritated and damaged scalp,<br/> - has experienced any reaction after colouring hair or eyelashes,<br/> - has experienced a reaction to a temporary "black henna" tattoo in the past.</p> <p>For professional use only.</p> |
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| 206 | 3-(2-Hydroxyethyl)- p-phenylenediammonium sulphate | Hydroxyethyl-p-Phenylenediamine Sulfate | 93841-25-9 | 298-995-1 | (a) Hair dye substance in oxidative hair dye products<br><br>(b) Products intended for colouring eyelashes | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (calculated as sulphate)<br><br>(b) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 1,75% (calculated as free base)<br><br>(b) Professional use | Rinse eyes immediately if product comes into contact with them.<br><br>(a) To be printed on the label:<br>The mixing ratio.<br> 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.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past.<br><br>(b) As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br>The mixing ratio.<br><br> 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 |
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| 211 | 2-Aminopyridin-3-ol | 2-Amino-3-Hydroxypyridine | 16867-03-1 | 240-886-8 | (a) Hair dye substance in oxidative hair dye products<br><br>(b) Products intended for colouring eyelashes | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %<br><br>(b) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 0,5 %<br><br>(b) Professional use | the risk of allergy.<br>Eyelashes shall not be coloured if the consumer:<br>- has a rash on the face or sensitive, irritated and damaged scalp,<br>- has experienced any reaction after colouring hair or eyelashes,<br>- has experienced a reaction to a temporary "black henna" tattoo in the past.<br><br>For professional use only.<br><br>Rinse eyes immediately if product comes into contact with them.<br><br>To be printed on the label:<br>The mixing ratio:<br> Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the |
|-----|---------------------|---------------------------|------------|-----------|--|---|---|


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|-----|---------------------------|--------------------|----------|-----------|---|--|---|
| 243 | 1,3-Benzenediol, 2-methyl | 2-Methylresorcinol | 608-25-3 | 210-155-8 | (a) Hair dye substance in oxidative hair dye products<br>(b) Hair dye | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,8 %<br><br>(b) 1,8 % | <p>past.</p> <p>(b) As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br/>The mixing ratio.</p> <p> This product can cause severe allergic reactions.<br/>Read and follow instructions.<br/>This product is not intended for use on persons under the age of 16. Temporary "black henna" tattoos may increase the risk of allergy.<br/>Eyelashes shall not be coloured if the consumer:<br/>- has a rash on the face or sensitive, irritated and damaged scalp,<br/>- has experienced any reaction after colouring hair or eyelashes,<br/>- 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> <p>(a) To be printed on the label:<br/>The mixing ratio.</p> <p> Hair colorants can cause severe allergic reactions.<br/>Read and follow instructions.</p> |
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|  |  |  |  | <p>substance in non-oxidative hair dye products</p> <p>(c) Products intended for colouring eyelashes</p> | <p>(c) After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 1,25%</p> <p>(c) Professional use</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"> <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> <p>(c) As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label: The mixing ratio.</p> <p> 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"> <li>- has a rash on the face or sensitive, irritated and damaged scalp,</li> <li>- has experienced any reaction after colouring hair</li> </ul> |
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|---|---------------|---------------|----------|-----------|---|---|---|
| 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>or eyelashes,<br/>- 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> |
| <p>(a) To be printed on the label:<br/>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.</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"> <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> <p>(b) As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br/>The mixing ratio.</p> |               |               |          |           |   |   |   |




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| 298 | butanoyl]aminoethyl][di-sulfanyl dichloride      | HC Yellow No. 17                     | 1450801-55-4 |  |  | after the date of entry into force of this Regulation]:<br>0,5% | entry into force of this Regulation]:<br>- Do not use with nitrosating agents<br>- Maximum nitrosamine content: 50 µg/kg<br>- Keep in nitrite-free containers | As from [date = 12 months after the date of entry into force of this Regulation]:<br> 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.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past.' |
| 299 | 1H-Pyrazole-4,5-diamine, 1-hexyl-, sulfate (2:1) | 1-Hexyl 4,5-Diamino Pyrazole Sulfate | 1361000-03-4 |  |  |   | As from [date = 6 months after the date of entry into force of this Regulation], after mixing under oxidative conditions the maximum concentration applied to | As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br>The mixing ratio.<br> Hair colorants can cause  |

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| 300 | 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 | As from [date = 6 months after the date of entry into force of this Regulation], after mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5% | <p>severe allergic reactions.<br/>Read and follow instructions.<br/>This product is not intended for use on persons under the age of 16.<br/>Temporary "black henna" tattoos may increase your risk of allergy.<br/>Do not colour your hair if:<br/>- you have a rash on your face or sensitive, irritated and damaged scalp,<br/>- you have ever experienced any reaction after colouring your hair,<br/>- you have experienced a reaction to a temporary "black henna" tattoo in the past.'</p>   |
|     |  |                                      |           |           |   | <p>hair must not exceed 1,0%</p>  | <p>As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br/>The mixing ratio.<br/> Hair colorants can cause severe allergic reactions.<br/>Read and follow instructions.<br/>This product is not intended for use on persons under the age of 16.<br/>Temporary "black henna" tattoos may increase your risk of allergy.<br/>Do not colour your hair if:<br/>- you have a rash on your face or sensitive, irritated and damaged scalp,<br/>- you have ever experienced any reaction after colouring</p> |



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| 301 | 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 | As from [date = 6 months after the date of entry into force of this Regulation], after mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0% | your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past.'  |
| 302 | 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 | As from [date = 6 months after the date of entry into force of this Regulation], after mixing under oxidative conditions the maximum concentration applied to hair must not exceed      | As from [date = 12 months after the date of entry into force of this Regulation], to be printed on the label:<br>The mixing ratio.<br> Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past.' |

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|     |   |                |            |           |   |  |  | 2,0%   | This product is not intended for use on persons under the age of 16.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face or sensitive, irritated and damaged scalp,<br>- you have ever experienced any reaction after colouring your hair,<br>- you have experienced a reaction to a temporary "black henna" tattoo in the past.' |
| 303 | 2-Naphthalenaminiium, 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 | As from [date = 6 months after the date of entry into force of this Regulation]:<br>2,0% |  |  |  |
| 304 | 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 | As from [date = 6 months after the date of entry into force of this Regulation]:<br>0,5% | As from [date = 6 months after the date of entry into force of this Regulation]:<br>- Do not use with nitrosating agents<br>- Maximum nitrosamine content: 50 µg/kg<br>- Keep in nitrite-free containers | As from [date = 12 months after the date of entry into force of this Regulation]:<br> Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary "black henna" tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>- you have a rash on your face |  |

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|  |  |  |  |  |  |  |  |  |  | <p>or sensitive, irritated and damaged scalp,<br/> - you have ever experienced any reaction after colouring your hair,<br/> - you have experienced a reaction to a temporary "black henna" tattoo in the past."</p> |
|--|--|--|--|--|--|--|--|--|--|---|