
STATUTORY INSTRUMENTS

2009 No. 2562

CONSUMER PROTECTION

**The Cosmetic Products (Safety)
(Amendment No.3) Regulations 2009**

*Made - - - - 21st September 2009
23rd September
Laid before Parliament 2009
Coming into force in accordance with regulation 1(2)*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 11 of the Consumer Protection Act 1987⁽¹⁾.

In accordance with section 11(5) of that Act the Secretary of State has consulted such organisations as appear to him to be representative of interests substantially affected by the following Regulations, such other persons as are considered appropriate and the Health and Safety Executive.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment No. 3) Regulations 2009.

(2) Regulation 2 shall come into force on 15th May 2010, except that in relation to Regulation 2(b)(ii)(bb) the deletion of the entry relating to reference number 57 shall come into force on 14th October 2009.

(3) In these Regulations “the Principal Regulations” means the Cosmetic Products (Safety) Regulations 2008⁽²⁾.

Amendment to the Principal Regulations

2. The Principal Regulations are amended as follows—

(a) in Schedule 2 delete the paragraphs after paragraph 55, and replace with paragraphs 56 to 59 in Schedule 1 to these Regulations.

(b) in Schedule 4—

(i) in Part 1, after entry 188 insert entries 189 to 205 set out in Schedule 2 to these Regulations; and

(1) 1987 c.43. Section 11(1) has been amended by S.I. 2005/1803, and section 11(5) has been amended by S.I. 2008/960.

(2) S.I. 2008/1284, as amended by S.I. 2008/2173, S.I. 2008/2566, S.I. 2009/796 and S.I. 2009/1346.

(ii) in Part 2—

- (aa) in columns “c” and “d” of the entry relating to reference number 55, section “b” is deleted;
- (bb) the entries relating to reference numbers 7, 9, 14, 18, 24, 28, 47, 57, and 58 are deleted.

21st September 2009

Kevin Brennan
Minister of State for Further Education, Skills,
Apprenticeships and Consumer Affairs
Department for Business, Innovation and Skills

SCHEDULE 1

Regulation 2(a)

- “56. Commission Directive 2008/88/EC (O.JNo. L256, 24.9.2008, p.12).
 57. Commission Directive 2008/123/EC (O.JNo. L340, 19.12.2008, p.71-72).
 58. Commission Directive 2009/6/EC (O.JNo. L36, 5.2.2009, p.15 - 17).
 59. Commission Directive 2009/36/EC (O.J. No L98, 17.4.2009, p.31 - 37).”

SCHEDULE 2

Regulation 2(b)(i)

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|---|---|------------------------------------|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 189 | Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate and aluminium lake ⁽¹¹⁾ Acid Yellow 23 CAS 1934-21-0 EINECS 217-699-5 Acid Yellow 23 Aluminum lake CAS 12225-21-7 EINECS 235-428-9 CI 19140 | Hair dye substance in non-oxidative hair dye products | 0.5% | | |
| 190 | Benzenemethanamine, N-ethyl-N-[4- | Aluminium, dye substance in | 0.5% | | |

(11) The free base and salts of this hair colouring ingredient, unless prohibited under Schedule 3, are permitted for use.

Status: This is the original version (as it was originally made).

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|---|---------------------------------|---|------------------------------------|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | [[4-[ethyl-(3-sulfophenyl)-methyl]-amino]-phenyl] [2-sulfophenyl)-methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo, inner salt, disodium salt and its ammonium and aluminium salts ⁽¹¹⁾ | non-oxidative hair dye products | | | |
| | Acid Blue 9 CAS 3844-45-9 EINECS 223-339-8 Acid Blue 9 Ammonium salt CAS 2650-18-2 EINECS 220-168-0 Acid Blue 9 Aluminum lake CAS 68921-42-6 EINECS 272-939-6 CI 42090 | | | | |

(11) The free base and salts of this hair colouring ingredient, unless prohibited under Schedule 3, are permitted for use.

Status: This is the original version (as it was originally made).

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|---|---|------------------------------------|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 191 | Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate ⁽¹¹⁾ Curry Red CAS 25956-17-6 EINECS 247-368-0 CI 16035 | Hair dye substance in non-oxidative hair dye products | 0.4% | | |
| 192 | Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4,6,8-trisulphonate and aluminium lake ⁽¹¹⁾ Acid Red 18 CAS 2611-82-7 EINECS 220-036-2 Acid Red 18 Aluminum lake CAS 12227-64-4 EINECS 235-438-3 CI 16255 | Hair dye substance in non-oxidative hair dye products | 0.5% | | |
| 193 | Hydrogen 3,6-bis(diethylamino) | (a) Hair dye substance in | | (a) After mixing under | (a) The mixing ratio must be |

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| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|---|---|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | (2,4-disulphonatophenyl) xanthylium, sodium salt ⁽¹¹⁾ Acid Red 52 CAS 3520-42-1 EINECS 222-529-8 CI 45100 | oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products | (b) 0.6% | oxidative conditions the maximum concentration applied to hair must not exceed 1.5%. | printed on the label. |
| 194 | Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate ⁽¹¹⁾ Acid Red 33 CAS 3567-66-6 EINECS 222-656-9 CI 17200 | Hair dye substance in non-oxidative hair dye products | 0.5% | | |
| 195 | Sodium 1-amino-4-(cyclohexylamino)-9,10-dioxoanthracene-2-sulphonate ⁽¹¹⁾ Acid Blue 62 CAS 4368-56-3 | Hair dye substance in non-oxidative hair dye products | 0.5% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | |

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| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|---|---|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | EINECS 224-460-9 CI 62045 | | | | |
| 196 | 1-[(2',-Methoxyethyl)amino]-2',-nitro-4-[di-(2',-hydroxyethyl)amino]benzene ⁽¹¹⁾ HC Blue No 11 CAS 23920-15-2 EINECS 459-980-7 | Hair dye substance in nonoxidative hair dye products | 2.0% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | |
| 197 | 1,5-Di-(β-hydroxyethylamino)-2',-nitro-4-chlorobenzene ⁽¹¹⁾ HC Yellow No 10 CAS 109023-83-8 EINECS 416-940-3 | Hair dye substance in nonoxidative hair dye products | 0.1% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | |
| 198 | 3-Methylamino-4-nitrophenoxyethanol 3-Methylamino-4-nitrophenoxyethanol (INCI) | Hair dye substance in nonoxidative hair dye products | 0.15% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg | |

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| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|---|---|---|---|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | CAS 59820-63-2 EINECS 261-940-7 | | | — Keep in nitrite-free containers | |
| 199 | 2,2',-[[4-[(2-hydroxyethyl)amino]-3-nitrophenyl]imino]bisethanol ⁽¹¹⁾ HC Blue No 2 CAS 33229-34-4 EINECS 251-410-3 | Hair dye substance in non-oxidative hair dye products | 2.8% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | Can cause allergic reaction |
| 200 | 1-Propanol, 3-[[4-[[bis(2-hydroxyethyl)amino]-2-nitrophenyl]amino]ethyl] ⁽¹¹⁾ HC Violet No 2 CAS 104226-19-9 EINECS 410-910-3 | Hair dye substance in non-oxidative hair dye products | 2.0% | — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | Can cause allergic reaction |
| 201 | Phenol, 2-chloro-6-(ethylamino)-4-nitro- ⁽¹¹⁾ | Hair dye substance in non-oxidative hair dye products | 3.0% | — Do not use with nitrosating systems | Can cause allergic reaction |

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| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|---|--|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | 2-Chloro-6-ethylamino-4-nitrophenol CAS 131657-78-8 EINECS 411-440-1 | | | — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers | |
| 202 | 4,4',-[1,3-Propanediylbis(oxo)]bis(bisbenzene-1,3-diamine and its tetrahydrochloride salt ⁽¹¹⁾) 1,3-bis-(2,4-Diaminophenoxy)propane CAS 81892-72-0 EINECS 279-845-4 1,3-bis-(2,4-Diaminophenoxy)-propane HCl CAS 74918-21-1 EINECS 278-022-7 | (a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.2 % calculated as free base (1.8 % as tetrahydrochloride salt). (b) 1.2 % as free base (1.8 % as tetrahydrochloride salt) | (a) The mixing ratio must be printed on the label. For (a) and (b): Can cause allergic reaction |
| 203 | 6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum | (a) The mixing ratio must be printed on the label. |

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| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|---|---|--|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| | and dihydrochloride salt ⁽¹¹⁾ 6-Methoxy-2-methylamino-3-aminopyridine HCl CAS 90817-34-8 (HCl) CAS 83732-72-3 (2HCl) EINECS 2180-622-9 2HCl | (b) Hair dye substance in non-oxidative hair dye | (b) 0.68 % as free base (1.0 % as dihydrochloride) | concentration applied to hair must not exceed 0.68 % calculated as free base (1.0 % as dihydrochloride). For (a) and (b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg | For (a) and (b): Can cause allergic reaction |
| | | | | — Keep in nitrite-free containers | |
| 204 | 2,3-Dihydro-1H-indole-5,6-diol and its hydrobromide salt ⁽¹¹⁾ Dihydroxyindoline CAS 29539-03-5 Dihydroxyindoline HBr CAS 138937-28-7 | Hair dye substance in non-oxidative hair dye products | 2.0% | | Can cause allergic reaction |

(11) The free base and salts of this hair colouring ingredient, unless prohibited under Schedule 3, are permitted for use.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 2008 (S.I. 2008/1284) (“the Principal Regulations”) to give effect to Commission Directive 2009/36/EC, (O.J. L98/31, 17.4.2009), as amended by corrigendum, (O.J. L103/30, 23.4.2009), and, in part, to Commission Directive 2008/88/EC (O.J. L256/12, 24.9.2008), as amended by corrigendum, (O.J. L263/26, 2.10.2008) (“the Directives”). Directive 2008/88 was partly implemented by S.I. 2009/796. The Directives amend Council Directive 76/768/EEC (O.J. No. L262, 27.9.76, p.169) on the approximation of the laws of the Member States on cosmetic products. Council Directive 76/768/EEC (as previously amended) has been implemented by the Principal Regulations.

Regulation 2(a) adds Directive 2009/36/EC to Schedule 2 to the Principal Regulations, namely, the list of Directives implemented by the Principal Regulations. It also corrects the paragraph numbering of the Directives listed in Schedule 2.

Regulation 2(b)(i) amends Part 1 of Schedule 4 to the Principal Regulations (list of substances which cosmetic products must not contain except subject to restrictions and conditions) and Regulation 2(b)(ii) amends Part 2 of Schedule 4 to the Principal Regulations (substances listed in Part 2 of Annex III to the Directive which are provisionally allowed). Regulation 2 shall come into force on 15 May 2010 except for the deletion of the entry relating to reference number 57 in Part 2 of Schedule 4 (Regulation 2(b)(ii)(bb)) which comes into force on 14 October 2009. The deletion of the entry relating to reference number 57 implements part of Directive 2008/88/EC.

An impact assessment has not been produced for this instrument as it has no significant impact on the costs of business.

Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department for Business, Innovation and Skills, 1 Victoria Street, London SW1H 0ET.