

2011 No. 3037

CONSUMER PROTECTION

The Cosmetic Products (Safety) (Amendment) Regulations 2011

Made - - - - *19th December 2011*

Laid before Parliament *20th December 2011*

Coming into force - - *3rd January 2012*

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

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) Regulations 2011.

(2) These Regulations come into force on 3rd January 2012.

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

Amendment to the Principal Regulations

2.—(1) The Principal Regulations are amended as follows.

(2) In Schedule 2 (list of Directives implemented by the Regulations) at the end insert—

“68. Commission Directive 2011/59/EU (OJ No L 125, 14.5.2011, p 17)”.

(3) In Schedule 3 (list of substances which must not form part of the composition of cosmetic products (unless otherwise specified)), after the entry with reference number 1371, insert the entry with reference number 1372 in Part 1 of the Schedule to these Regulations.

(4) In Part 1 of Schedule 4 (list of substances which cosmetic products must not contain except subject to restrictions and conditions)—

(a) for the entry with reference number 201 substitute the entry with that number in Part 2 of the Schedule to these Regulations; and

(a) 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.

(b) S.I. 2008/1284, as amended by S.I. 2008/2173, 2008/2566, 2009/796, 2009/1346, 2009/2562, 2009/3367, 2010/1150, 2010/1927, 2011/881 as regards England and SI 2011/2377 (W.250) as regards Wales; there is another amending instrument but it is not relevant.

(b) after the entry with reference number 209, insert the entries with reference numbers 215 to 218, 222, 223, 225, 227, 230, 232, 234, 237 to 239, 241 to 246, 248 to 252 in Part 2 of the Schedule to these Regulations.

(5) In Part 2 of Schedule 4 (substances listed in Part 2 of Annex III to the Directive which are provisionally allowed)—

- (a) omit the entries with reference numbers 3 to 6, 11, 12, 16, 19 to 22, 25, 27, 31 to 39, 44, 48, 49, 55 and 56; and
- (b) in the entries with reference numbers 10 and 50, in column “g”, for “31.12.2010” substitute “31.12.2011”.

19th December 2011

Edward Davey
Minister for Employment Relations, Consumer and Postal Affairs
Department for Business, Innovation and Skills

THE SCHEDULE Regulation 2(2) to (5)
**AMENDMENTS TO SCHEDULES 3 AND 4 OF THE PRINCIPAL
REGULATIONS**

PART 1

Amendments to Schedule 3

Ref. No	Chemical name	CAS No/EC No
1372	2-Aminophenol (o-Aminophenol; CI 76520) and its salts	CAS No 95-55-6/67845-79- 8/51-19-4 EC No 202-431- 1/267-335-4

PART 2

Amendments to Part 1 of Schedule 4

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Max authorised concentration in the finished cosmetic product	Other limitations and requirements	
<i>a</i>	<i>b</i>	<i>c</i>	<i>d</i>	<i>e</i>	<i>f</i>
201	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) (EC No 411-440-1)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 3.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
215	4-amino-3-nitrophenol (CAS No 610-81-1) (EC No 210-236-8)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f

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a	b	c	d	e	f
216	2,7-Naphthalenediol (CAS No 582-17-2) (EC No 209-478-7)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	(a) As mentioned in reference number 205, column f (a)
217	m-Aminophenol (CAS No 591-27-5) (EC No 209-711-2) and its salts m-Aminophenol HCl (CAS No 51-81-0) (EC No 200-125-2) m-Aminophenol sulphate (CAS No 68239-81-6) (EC No 269-475-1) sodium m-Aminophenol (CAS No 38171-54-9)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.2 %	As mentioned in reference number 205, column f (a)
218	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) (EC No 283-141-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	As mentioned in reference number 205, column f (a)
222	2-Hydroxyethyl picramic acid (CAS No 99610-72-7) (EC	(a) Hair dye substance in oxidative hair dye		(a) After mixing under oxidative conditions the	(a) As mentioned in reference number 205, column f (a)

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	No 412-520-9)	products		maximum concentration applied to hair must not exceed 1.5 %	
		(b) Hair dye substance in oxidative hair dye products	(b) 2.0%	For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
223	p-Methylaminophenol (CAS No 150-75-4) (EC No 205-768-2) and its sulphate p-Methylaminophenol sulphate (CAS No 55-55-0/1936-57-8) (EC No 200-237-1/217-706-1)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.68 % (as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
225	Ethanol, 2-[4- [Ethyl]-(2-Hydroxyethyl)Amino]-2-Nitrophenyl]- Amino]-, (CAS No 104516-93-0) and its hydrochloride	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.75 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)

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<i>a</i>	<i>b</i>	<i>c</i>	<i>d</i>	<i>e</i>	<i>f</i>
	HC Blue No 12 (CAS No 132885-85-9) (EC No 407-020-2)	(b) Hair dye substance in non-oxidative hair dye products	(b) 1.5 % (as hydrochloride)	For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
227	3-Amino-2,4-dichlorophenol (CAS No 61693-42-3) (EC No 262-909-0) and its hydrochloride 3-Amino-2,4-dichlorophenol HCl (CAS No 61693-43-4)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)
230	Phenyl methyl pyrazolone (CAS No 89-25-8) (EC No 201-891-0)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 %	As mentioned in reference number 205, column f (a)
232	2-Methyl-5-hydroxyethylamino-phenol (CAS No 55302-96-0) (EC No 259-583-7)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % — Do not use with nitrosating agents — Maximum nitrosamine	As mentioned in reference number 205, column f (a)

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				content: 50 µg/kg — Keep in nitrite-free containers	
234	Hydroxybenzomorpholine (CAS No 26021-57-8) (EC No 247-415-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 % — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrate-free containers	As mentioned in reference number 205, column f (a)
237	2,2'-[(4-Amino-3-nitrophenyl)imino]bisethanol (CAS No 29705-39-3) and its hydrochloride HC Red No 13 (CAS No 94158-13-1) (EC No 303-083-4)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2.5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.25 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)
238	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3 (free base)) and its hydrochloride	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 % (as hydrochloride)	As mentioned in reference number 205, column f (a)

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239	2,6-Dimethoxy-3,5-pyridinediamine HCl (CAS No 56216-28-5) (EC No 260-062-1) HC Violet No 1 (CAS No 82576-75-8) (EC No 417-600-7)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,28 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
241	1,5-Naphthalenediol (CAS No 83-56-7) (EC No 201-487-4)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	(a) As mentioned in reference number 205, column f (a)
242	Hydroxypropyl bis(N-hydroxyethyl)-p-	Hair dye substance in oxidative hair dye		After mixing under oxidative conditions the maximum	As mentioned in reference number 205, column f (a)

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	phenylenediamine) (CAS No 128729-30-6) and its tetrahydrochloride Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (CAS No 128729-28-2) (EC No 416-320-2)	products		concentration applied to hair must not exceed 0.4 % (as tetrahydrochloride)	
243	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) (EC No 220-618-6)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	As mentioned in reference number 205, column f (a)
244	2,4-Diaminophenoxyethanol (CAS No 70643-19-5), its hydrochloride and its sulphate 2,4-Diaminophenoxyethanol HCl (CAS No 66422-95-5) (EC No 266-357-1) 2,4-Diaminophenoxyethanol sulphate (CAS No 70643-20-8) (EC No 274-713-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % (as hydrochloride)	As mentioned in reference number 205, column f (a)
245	2-Methylresorcinol (CAS No 608-25-3) (EC No 210-155-8)	(a) Hair dye substance in oxidative hair dye		(a) After mixing under oxidative conditions the	(a) As mentioned in reference number 205, column f (a)

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		products		maximum concentration applied to hair must not exceed 1.8 %	
		(b) Hair dye substance in non-oxidative hair dye products	(b) 1.8 %		
246	4-Amino-m-cresol (CAS No 2835-99-6) (EC No 220-621-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	As mentioned in reference number 205, column f (a)
248	2-Amino-4-hydroxyethylaminoanisole (CAS No 83763-47-7) (EC No 280-733-2) and its sulphate 2-Amino-4-hydroxyethylaminoanisole sulphate (CAS No 83763-48-8) (EC No 280-734-8)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
249	Hydroxyethyl-3,4-methylenedioxyaniline and its hydrochloride Hydroxyethyl-3,4-	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % — Do not use with nitrosating	As mentioned in reference number 205, column f (a)

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	methylenedioxyaniline HCl (CAS No 94158-14-2) (EC No 303-085-5)			agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
250	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) (EC No 265-648-0)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.85 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3.0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
251	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) (EC No 410-700-1)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0.5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine	(a) As mentioned in reference number 205, column f (a)

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252	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) (EC No 228-762-1)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2.0%	content: 50 µg/kg — Keep in nitrite-free containers (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the Principal Regulations”) to give effect to Commission Directive 2011/59/EU (OJ No L 125, 14.5.2011, p 17). The Commission Directive amends Council Directive 76/768/EEC of 27 July 1976 (OJ No L 262, 27.9.1976, p 169) on the approximation of the laws of the Member States on cosmetic products (“the Cosmetics Directive”). The Cosmetics Directive (as previously amended) has been implemented by the Principal Regulations.

Regulation 2(2) adds the Commission Directive to Schedule 2 to the Principal Regulations, namely, the list of Directives implemented by the Principal Regulations.

Regulation 2(3) amends Schedule 3 to the Principal Regulations (list of substances which must not form part of the composition of cosmetic products (unless otherwise specified)) by adding an additional substance to the list of prohibited substances.

Regulation 2(4) 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), by including substances used in hair dye products, the use of which was previously only provisionally allowed.

Regulation 2(5) amends Part 2 of Schedule 4 to the Principal Regulations (substances listed in Part 2 of Annex III to the Cosmetics Directive which are provisionally allowed) by removing references to the substances used in hair dye products to be included in Part 1 of Schedule 4 by virtue of regulation 2(4) and to extend the period for the provisional use of two substances used in hair dye products until 31.12.2011.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Advanced Manufacturing and Services Group, Department for Business, Innovation and Skills (BIS), 1 Victoria Street, London SW1H 0ET. As these Regulations transpose a Directive, a transposition note setting out how the Government has transposed the Directive in the United Kingdom has been prepared. These documents are published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

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STATUTORY INSTRUMENTS

2011 No. 3037

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