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 accordan	ce 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.

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

21st September 2009

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	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
a	b	с	d	e	f
189	Trisodium 5- hydroxy-1-(4- sulphophenyl) -4-(4- sulphophenylaze 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	Benzenemethan Nethyl-N-[4-	a Hain ium, dye substance in	0.5%		

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	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	non-oxidative hair dye products			
	salts ⁽¹¹⁾				
	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				

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	d	e	f
191		Hair dye substance in non-oxidative hair dye products	0.4%		
	CAS 25956-17-6 EINECS 247-368-0				
	CI 16035				
192	Trisodium 1- (1- naphthylazo)-2- hydroxynaphtha trisulphonate and aluminium lake ⁽¹¹⁾	substance in non-oxidative	0.5%		
	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				
193	Hydrogen 3,6- bis(diethylaming	(a) Hair dye ogefostance in			(a) The mixing ratio must be

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	d	e	f
	(2,4- disulphonatophe xanthylium, sodium salt ⁽¹¹⁾ Acid Red 52 CAS 3520-42-1	oxidative hair not have been been been been been been been be		oxidative conditions the maximum concentration applied to hair must not exceed 1.5%.	printed on the label.
	EINECS 222-529-8	(b) Hair dye substance in	(b) 0.6%		
	CI 45100	non-oxidative hair dye products			
194	amino-4- hydroxy-3-	Hair dye substance in non-oxidative hthailene-2,7-dye products	0.5%		
	Acid Red 33 CAS				
	3567-66-6 EINECS 222-656-9				
	CI 17200				
195	Sodium 1- amino-4- (cyclohexylamin dihydro-9,10- dioxoanthracene sulphonate ⁽¹¹⁾	substance in na)>90,00 dative hair dye	0.5%	 — Do not use with nitrosating systems — Maximum nitrosamine content: 50 μg/ kg 	
	Acid Blue 62 CAS 4368-56-3			— Keep in nitrite-free containers	

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	d	e	f
	EINECS 224-460-9 CI 62045				
196	1-[(2',- Methoxyethyl) amino]-2',- nitro-4-[di-(2',- hydroxyethyl) amino] benzene ⁽¹¹⁾	Hair dye substance in nonoxidative hair dye products	2.0%	— Do not use with nitrosating systems	
	HC Blue No 11 CAS 23920-15-2 EINECS 459-980-7			 Maximum nitrosamine content: 50 μg/ kg Keep in nitrite-free containers 	
197	1,5-Di-(ß- hydroxyethylam nitro-4- chlorobenzene ⁽¹¹ HC Yellow No 10 CAS 109023-83-8 EINECS 416-940-3	i sud) stance in nonoxidative	0.1%	 Do not use with nitrosating systems Maximum nitrosamine content: 50 μg/ kg Keep in nitrite-free containers 	
198	 3- Methylamino-4- nitrophenoxyeth 3- Methylamino-4- nitrophenoxyeth (INCI) 	substance in ano1 ⁴⁰ xidative hair dye products	0.15%	 — Do not use with nitrosating systems — Maximum nitrosamine content: 50 μg/ kg 	

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	d	e	f
	CAS 59820-63-2 EINECS 261-940-7			— Keep in nitrite-free containers	
199	2,2',-[[4-[(2- hydroxyethyl) amino]-3- nnitrophenyl]im HC Blue No 2 CAS 33229-34-4 EINECS 251-410-3	Hair dye substance in non-oxidative ihaipbisethandy ^(H) 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)ari nitrophenyl]ami HC Violet No 2 CAS 104226-19-9 EINECS 410-910-3	substance in ninon-2xidative nhaji ⁽¹⁾ dye	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⁾	substance in	3.0%	— Do not use with nitrosating systems	Can cause allergic reaction

Reference	Substance		Restrictions		Conditions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	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(bisbenzene-1,3- diamine and its tetrahydrochlori salt ⁽¹¹⁾ 1,3-bis-(2,4- Diaminophenox propane CAS 81892-72-0 EINECS 279-845-4	oxidative hair dye products de (b) Hair dye			
	279-843-4 1,3-bis-(2,4- Diaminophenox propane HCl CAS 74918-21-1 EINECS 278-022-7	y)-	(b) 1.2 % as free base (1.8 % as tetrahydrochlori salt)	l	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) The mixing ratio must be printed on the label.

Conditions

Substance	Restrictions	

Reference

Rejerence	Substance		Restrictions		Conulions
number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
а	b	с	d	e	f
	and dihydrochloride salt ⁽¹¹⁾ 6-Methoxy-2- methylamino-3- aminopyridine HCl CAS 90817-34-8 (HCl)			concentration applied to hair must not exceed 0.68 % calculated as free base (1.0 % as dihydrochloride).
	CAS 83732-72-3 (2HCl) EINECS 2180-622-9 2HC1	(b) Hair dye substance in non-oxidative hair dye		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⁾	Hair dye substance in non-oxidative hair dye products	2.0%		Can cause allergic reaction
	Dihydroxyindol CAS 29539-03-5 Dihydroxyindol HBr				
	CAS 138937-28-7				

Reference	Substance		Restrictions		Conditions
number		Field of	Maximum	Other	of use and
		application	authorised	limitations	warnings
		and/or use	concentration	and	which must
			in the	requirements	be printed
			finished		on the label
			cosmetic		
			product		
a	b	с	d	e	f
	EINECS 421-170-6				
205	4- Hydroxypropyla nitrophenol ⁽¹¹⁾ 4- Hydroxypropyla nitrophenol (INCI) CAS 92952-81-3 EINECS 406-305-9	oxidative hair dye products	(b) 2.6%	 (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.6 % calculated as free base. For (a) and (b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 μg/kg — Keep in nitrite-free containers 	(a) The mixing ratio must be printed on the label.

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.