STATUTORY INSTRUMENTS

2010 No. 1150

CONSUMER PROTECTION

The Cosmetic Products (Safety) (Amendment) Regulations 2010

Made---29th March 2010Laid before Parliament6th April 2010Coming into force in accordance with regulation 1(2)to (9)

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) Regulations 2010.

(2) Regulations 2(b), 2(d)(i) and 2(d)(v) shall come into force on 15th July 2010.

(3) Regulation 2(d)(viii) shall come into force on 15th October 2010.

(4) Regulation 2(e)(vii), shall come into force on 1st December 2010.

(5) Regulation 2(d)(xiv), save for the entry in column 'f' opposite reference number 208 of Part 1 to Schedule 4, shall come into force on 1st December 2010 and in relation to that entry, shall come into force on 1st November 2011, subject to Regulation (1D) in the Principal Regulations.

(6) Regulation 2(a) shall come into force on 15th February 2011.

(7) Regulations 2(c), 2(d)(ix), 2(d)(x) and 2(d)(xii) shall come into force on 15th February 2011, subject to Regulation (1C) in the Principal Regulations.

(8) Regulations 2(d)(xiii), 2(d)(xv) and 2(f) shall come into force on 1st March 2011.

(9) Regulations 2(d)(ii) to 2(d)(iv), 2(d)(vi), 2(d)(vii), 2(d)(xi) and 2(e)(i) to 2(e)(vi) shall come into force on 1st November 2011, subject to Regulation (1D) in the Principal Regulations.

(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.

(10) 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 Regulation 2, after paragraph (1B) insert—
 - "(1C) Cosmetic products which fail to comply with-
 - (a) the second column opposite reference number 450 of Schedule 3 to these Regulations; or
 - (b) column 'b' opposite reference number 130 in Part 1 of Schedule 4 to these Regulations; or
 - (c) the entries opposite reference number 151a in Part 1 of Schedule 4 to these Regulations,

may not be placed on the market by EEA manufacturers or by importers established within the EEA after 15th February 2011 and may not be sold or disposed of to the final consumer in the EEA after 15th August 2011.

(1D) Cosmetic products which fail to comply with—

- (a) column 'f' of the entries opposite reference numbers 8, 8a, 9, 9a, 16, 22, 193, 202, 203, 205 and 208 in Part 1 of Schedule 4; or
- (b) column 'f' of the entries opposite reference numbers 3 to 6, 10 to 12, 16, 19 to 22, 25 to 27, 31 to 39, 44, 48 to 50, 55 and 56, of Part 2 of Schedule 4,

may not be placed on the market by EEA manufacturers or by importers established within the EEA after 1st November 2011 and may not be sold or disposed of to the final consumer in the EEA after 1st November 2012.";

- (b) in Schedule 2 insert at the end—
 - "61. Commission Directive 2009/129/EC (O.J. No L267, 10.10.2009, p.18).
 - 62. Commission Directive 2009/130/EC (O.J. No L268, 13.10.2009, p.5).
 - 63. Commission Directive 2009/134/EC (O.J. No L282, 29.10.2009, p.15).
 - 64. Commission Directive 2009/164/EU (O.J. No L344, 23.12.2009, p.41)
 - 65. Commission Directive 2010/3/EU (O.J. No L29, 2.2.2010, p.5)
 - 66. Commission Directive 2010/4/EU (O.J. No L36, 9.2.2010, p.21)";
- (c) In Schedule 3, in the entries opposite reference number 450, in the second column substitute "Verbena essential oils *(Lippia citriodora* Kunth.) and derivatives other than absolute when used as a fragrance ingredient";
- (d) in Part 1 of Schedule 4-
 - (i) after the entries opposite reference number 7 delete the entries for reference numbers 8 and 9 and insert the entries for reference numbers 8, 8a, 9 and 9a in Schedule 1 to these Regulations;
 - (ii) in column 'f' opposite reference numbers 8 and 8a for "Can cause allergic reaction" and "Can cause an allergic reaction" in paragraphs (a) and (b) substitute the contents of Schedule 2 to these Regulations;

⁽²⁾ S.I. 2008/1284, as amended by S.I. 2008/2173, S.I. 2008/2566, S.I. 2009/796, S.I. 2009/1346, S.I. 2009/2562 and S.I. 2009/3367.

- (iii) in column 'f' opposite reference numbers 8a and 9a, at the end of paragraphs (a) and (b) insert, "The mixing ratio is printed on the label.";
- (iv) for the entries opposite column 'f' of reference numbers 9 and 9a substitute the contents of Schedule 3;
- (v) in relation to the entries opposite reference number 14-

(aa) delete "0.3%," in column 'd';

- (bb) in column 'f' delete paragraph (a);
- (vi) in column 'f' opposite reference numbers 16, 202 and 203 for "Can cause allergic reaction" substitute the contents of Schedule 2 to these Regulations;
- (vii) in column 'f' opposite reference number 22 after paragraph (a) insert the contents of Schedule 2 to these Regulations;
- (viii) in column 'f' opposite reference numbers 26 to 43, 47 and 56 delete the first sentence and insert—

"For any toothpaste with compounds containing fluorine in a concentration of 0.1 to 0.15% calculated as F unless it is already labelled as contra-indicated for children (e.g. "for adult use only") the following labelling is obligatory:

"Children of 6 years and younger: use a pea sized amount for supervised brushing to minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.""

- (ix) in column 'b' opposite reference number 130 for "Terpene terpenoids sinpine" substitute "Terpenes and terpenoids";
- (x) after the entries opposite reference number 151 insert the entries for reference number 151a in Schedule 1 to these Regulations;
- (xi) in column 'f' opposite reference numbers 193 and 205 after paragraph (a) insert the contents of Schedule 2 to these Regulations;
- (xii) after the entries opposite reference number 205 insert the entries for reference number 206 in Schedule 1 to these Regulations;
- (xiii) after the entries opposite reference number 206 insert the entries for reference number 207 in Schedule 1 to these Regulations;
- (xiv) after the entries opposite reference number 207 insert the entries for reference numbers 208 and 209 in Schedule 1 to these Regulations;
- (xv) at the end of Part 1 of Schedule 4, after the last footnote insert "(*) For use as a preservative, see Schedule 6, Part 1, reference number 58.";
- (e) In Part 2 of Schedule 4—
 - (i) in column 'f' opposite reference number 3 for "Can cause allergic reaction" substitute the contents of Schedule 2 to these Regulations;
 - (ii) in column 'f' opposite reference numbers 4, 20, 26, 32, 34 to 39 and 44 insert the contents of Schedule 2 to these Regulations;
 - (iii) in column 'f' opposite reference numbers 5, 6, 12, 19, 21, 22, 25 and 33 for "Can cause allergic reaction" substitute the contents of Schedule 2 to these Regulations;
 - (iv) in column 'f' opposite reference numbers 10, 11 and 16-
 - (aa) in paragraph (a) for "Can cause allergic reaction" substitute the contents of Schedule 2 to these Regulations;
 - (bb) delete paragraph (b);

- (v) in column 'f' opposite reference numbers 27, 48 and 56 insert the contents of Schedule 4 to these Regulations;
- (vi) in column 'f' opposite reference numbers 31, 49, 50 and 55 insert "(a)" and the contents of Schedule 2 to these Regulations;
- (vii) the entries opposite reference numbers 26 and 29 are deleted;
- (f) In Part 1 of Schedule 6, after the entries opposite reference number 57 insert the entries for reference number 58 in Schedule 5 to these Regulations.

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

29th March 2010

SCHEDULE 1

Regulations 2(d)(i), 2(d)(x), 2(d)(xii) to 2(d)(xiv) and 2(e)(vii)

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
8	N-substituted derivatives of p- Phenylenediami and their salts; N-substituted derivatives of o- Phenylenediami (¹), with exception of those	agents for hair nebyeing	6 % calculated as free base, subject to the provisions of "Combination Rule A" at the end of this Schedule.		
	derivatives listed elsewhere in this Schedule and under reference numbers 1309, 1311, and 1312 in Schedule 3.				
		(a) general use			(a) Can cause allergic reaction. Contains phenylenediamine Do not use to dye eyelashes or eyebrows.
		(b) professional use			(b) For professional use only. Contains phenylenediamine Can cause an allergic reaction. Wear

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
					suitable gloves.
8a	p- Phenylenediami and its salts(¹).	Hair dye næubstance in oxidative hair dye products		(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % calculated as free base	(a) Can cause an allergic reaction. Contains phenylenediamin. Do not use to dye eye lashes or eyebrows.
	CAS No 106-50-3	(a) general use			(b) For professional use only. Contains phenylenediamin Can cause an allergic
	Einecs 203-404-7	(b) professional use			reaction. Wear suitable gloves.
	p- Phenylediamine HCl				
	CAS No 624-18-0				
	Einecs 210-834-9				
	p- Phenylenediami sulphate	ne			
	CAS No 16245-77-5				

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
	Einecs 240-357-1				
9	Methylphenyler their N- substituted derivatives and their salts (¹) with the exception of the substance under reference number 9a in this Schedule and substances under reference numbers 364, 1310 and 1313 in Schedule 3.	colouring agents for hair	10% calculated as free base, subject to the provisions of "Combination Rule A" at the end of this Schedule.		
		(a) general use(b) professional use			 (a) Can cause an allergic reaction. Contains phenylenediamin Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylenediamin Can cause an allergic reaction. Wear suitable gloves.

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	
9a	Toluene-2,5- diamine and its salts ⁽¹⁾ CAS No 95-70-5 Einecs 202-442-1 Toluene-2,5- diamine sulphate CAS No 615-50-9 Einecs 210-431-8	Hair dye substance in oxidative hair dye products (a) general use (b) profession use		(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 4 % calculated as free base.	 (a) Can cause an allergic reaction. Contains phenylenedi Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylenedi Can cause an allergic reaction. 	1
1.51	A 11 - 1				gloves.	
151a	Allyl phenethyl ether CAS No 14289-65-7 EC No 238-212-2			Level of free allyl alcohol in the ether should be less than 0.1%.		
206	Verbena absolute (Lippia citriodora Kunth) CAS No 8024-12-2		0.2%			

ce Substance						
μ	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		
b	с	d	e	f		
Ethyl Lauroyl Arginate HCl (INCI) (*)	(a) soap	0.8%	For purposes other than inhibiting the development of micro- organisms in the product.			
Ethyl-N ^α – dodecanoyl- L-arginate hydrochloride	(b) anti- dandruff shampoo		This purpose has to be apparent from the presentation of the product.			
CAS No 60372-77-2 EC No 434-630-6	(c) deodorants, not in form of spray					
434-030-01-(beta- Aminoethyl)am (beta-hydro- xyethyl)oxy-2- nitro-benzene and its salts		1.0%	—Do not use with nitrosating systems			
HC Orange No 2			Maximum nitro- samine content: 50 μ _{g/kg}	H colorants can cause severe allergic reactions.		
CAS No 85765-48-6 EINECS			—Keep in nitrite-free containers	Read and follow instructions. This product is not intended		
85765-	48-6 S	48-6 S	48-6 S	48-6 nitrite-free containers S 0-1		

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		
а	b	с	d	e	f
					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.
09	2-[(2-	Hair dye	0.2%	—Do not use	
	methoxy-4- nitro-	substance in non-oxidative		with nitrosating	
	phenyl)amino]e and its salts	t hannol dye products		systems	
	2- Hydroxyethylan	nino-		—Maximum nitro-samine content:	

Reference	Substance		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
	5-nitroanisole CAS No 66095-81-6			$50 \mu_{g/kg}$ —Keep in nitrite-free containers	
	EINECS 266-138-0				

SCHEDULE 2

Regulations 2(d)(ii), 2(d)(vi), 2(d)(vii), 2(d)(xi), 2(e)(i) to 2(e)(iv)(aa)and 2(e)(vi)

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.

SCHEDULE 3

Regulation 2(d)(iv)

Hair colorants can cause severe allergic reactions. (a) 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.

Contains phenylenediamines (toluenediamines).

Do not use to dye eyelashes or eyebrows.

(b) For professional use only.

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,
- your have experienced any reaction to a temporary "black henna" tattoo in the past.

Contains phenylenediamines (toluendiamines). Wear suitable gloves.

SCHEDULE 4

Regulation 2(e)(v)

(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.

(b) 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.

SCHEDULE 5

Regulation 2(f)

Reference number	Substances	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
а	b	с	d	e
58	Ethyl Lauroyl Arginate HCl (INCI) ⁽⁵⁾ Ethyl-N ^A – dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	0.4%	Not to be used in lip products, oral products and spray products.	

(5) For uses other than preservatives see Schedule 4, Part 1, reference number 207.

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 2009/129 of 9 October 2009 (OJ L267 of 10.10.2009, p18), Commission Directive 2009/130/EC of 12 October 2009 (OJ No L268, 13.10.2009 p.5), Commission Directive 2009/134/EC of 28 October 2009 (OJ No L282, 29.10.2009 p.15), Commission Directive 2009/164/EU of 22 December 2009 (OJ No L349 23.12.2009, p.41), as amended by Corrigendum (OJ No L3, 7.1.2010, p. 30), Commission Directive 2010/3/EU of 1 February 2010/3/EU (OJ No L29, p5) and Commission Directive 2010/4/EU (OJ No L36, 9.2.2010 p.21) ("the Directives"). The Directives amend Council Directive 76/768/EEC of 27 July 1976 (OJ No L262 27.9.1976 p169) on the approximation of the laws of the Member States on cosmetic products ("the Principal Directive"). The Principal Directive (as previously amended) has been implemented by the Principal Regulations.

Regulation 2(a) inserts transitional provisions into Regulation 2 to the Principal Regulations.

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

Regulation 2(c) amends Schedule 3 to the Principal Regulations (List of Substances which must not form part of the composition of cosmetic products (unless otherwise specified)).

Regulation 2(d) 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), including making changes to the labelling requirements for hair dye products.

Regulation 2(d)(i) also makes corrections to the entries opposite reference number 9 in Part 1 of Schedule 4.

Regulation 2(e) 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(f) amends Part 1 of Schedule 6 to the Principal Regulations (List of preservatives allowed).

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

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.