

**2010 No. 1150**

**CONSUMER PROTECTION**

**The Cosmetic Products (Safety) (Amendment) Regulations 2010**

*Made* - - - - *29th March 2010*

*Laid before Parliament* *6th April 2010*

*Coming 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(a).

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.

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

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(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, S.I. 2008/2566, S.I. 2009/796, S.I. 2009/1346, S.I. 2009/2562 and S.I. 2009/3367.

## 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;
- (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



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	
8a	<p><i>b</i></p> <p>p-Phenylenediamine and its salts<sup>(1)</sup>.</p> <p>CAS No 106-50-3</p> <p>Einecs 203-404-7</p> <p>p-Phenylenediamine HCl</p> <p>CAS No 624-18-0</p> <p>Einecs 210-834-9</p> <p>p-Phenylenediamine sulphate</p> <p>CAS No 16245-77-5</p> <p>Einecs 240-357-1</p>	<p><i>c</i></p> <p>Hair dye substance in oxidative hair dye products</p> <p>(a) general use</p> <p>(b) professional use</p>	<p><i>d</i></p>	<p><i>e</i></p> <p>(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % calculated as free base</p>	<p><i>f</i></p> <p>(a) Can cause an allergic reaction. Contains phenylenediamines. Do not use to dye eye lashes or eyebrows.</p> <p>(b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Wear suitable gloves.</p>
9	<p>Methylphenylenediamines, their N-substituted derivatives and their salts ( <sup>1</sup> ) with the exception of the substance under reference number 9a in this Schedule and substances under reference numbers 364,</p>	<p>Oxidizing colouring agents for hair dyeing</p>	<p>10% calculated as free base, subject to the provisions of "Combination Rule A" at the end of this Schedule.</p>		

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 1310 and 1313 in Schedule 3.	c	d	e	f
		(a) general use  (b) professional use			(a) Can cause an allergic reaction. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Wear suitable gloves.
9a	Toluene-2,5-diamine and its salts <sup>(1)</sup>  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) professional 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 phenylenediamines. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Wear suitable gloves.

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	
		<i>c</i>	<i>d</i>	<i>e</i>	<i>f</i>
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 ( <i>Lippia citriodora Kunth</i> ) CAS No 8024-12-2		0.2%		
207	Ethyl Lauroyl Arginate HCl (INCI) (*)  Ethyl-N <sup>α</sup> -dodecanoyl-L-arginate hydrochloride  CAS No 60372-77-2 EC No 434-630-6	(a) soap  (b) anti-dandruff shampoo  (c) deodorants, not in form of spray	0.8%	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
208	1-(beta-Aminoethyl)amino-4-(beta-hydroxyethyl)oxy-2-nitrobenzene and its salts	Hair dye substance in non-oxidative hair dye products	1.0%	—Do not use with nitrosating systems	





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		Field of application and/or use	Maximum 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>
209	2-[(2-methoxy-4-nitro-phenyl)amino]ethanol and its salts 2-Hydroxyethylamino-5-nitroanisole CAS No 66095-81-6 EINECS 266-138-0	Hair dye substance in non-oxidative hair dye products	0.2%	—Do not use with nitrosating systems —Maximum nitrosamine content: 50 µg/kg —Keep in nitrite-free containers	—you have experienced a reaction to a temporary “black henna” tattoo in the past.

## 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)



(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.

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)

<i>Reference number</i>	<i>Substances</i>	<i>Maximum authorised concentration</i>	<i>Limitations and requirements</i>	<i>Conditions of use and warnings which must be printed on the label</i>
a	b	c	d	e
58	Ethyl Lauroyl Arginate HCl (INCI) <sup>(5)</sup>  Ethyl-N <sup>α</sup> – 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.	

<sup>(5)</sup> 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.

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STATUTORY INSTRUMENTS

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**2010 No. 1150**

**CONSUMER PROTECTION**

The Cosmetic Products (Safety) (Amendment) Regulations 2010

£5.50