



STATUTORY INSTRUMENTS.

S.I. No. 194 of 2010

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) REGULATIONS 2010

(Prn. A10/0622)

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) REGULATIONS 2010

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Directives 2009/129/EC¹ of 9 October 2009, 2009/130/EC² of 12 October 2009, 2009/134/EC³ of 28 October 2009, 2009/159/EU⁴ of 16 December 2009, 2009/164/EU⁵ of 22 December 2009 and 2010/3/EU⁶ of 1 February 2010 and to Directive 2008/112/EC⁷ of the European Parliament and of the Council of 16 December 2008, hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2010.

Collective citation and construction

2. The European Communities (Cosmetic Products) Regulations 2004 to 2009 and these Regulations may be cited together as the European Communities (Cosmetic Products) Regulations 2004 to 2010 and shall be construed together as one.

Commencement

3. (1) Subject to paragraphs (2) to (7), these Regulations come into operation on 10 May 2010.

(2) (a) Subject to subparagraph (b), Schedule 1 comes into operation on 1 June 2010.

(b) Paragraph 2 of that Schedule comes into operation on 1 December 2010.

(3) Schedule 2 comes into operation on 15 October 2010.

(4) Schedule 3 comes into operation on 15 July 2010.

(5) (a) Subject to subparagraph (b), Schedule 4 comes into operation on 1 November 2011.

¹OJ No. L267, 10.10.2009, p18

²OJ No. L268, 13.10.2009, p6

³OJ No. L282, 29.10.2009, p15

⁴OJ No. L336, 18.12.2009, p29

⁵OJ No. L344, 23.12.2009, p41

⁶OJ No. L29, 2.2.2010, p5

⁷OJ No. L345, 23.12.2008, p68

*Notice of the making of this Statutory Instrument was published in
"Iris Oifigiúil" of 11th May, 2010.*

- (b) Insofar as a cosmetic product fails to comply with a requirement provided for in Schedule 4, the prohibition on its sale or disposal to the final consumer comes into operation on 1 November 2012.
- (6) (a) Subject to subparagraph (b), Schedule 6 comes into operation on 15 February 2011,
 - (b) Insofar as a cosmetic product fails to comply with a requirement provided for in Schedule 6, the prohibition on its sale or disposal to the final consumer comes into operation on 15 August 2011.
- (7) Schedule 7 comes into operation on 1 March 2011.

Interpretation

4. In these Regulations, “Principal Regulations” means the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004), as amended.

Amendment of Regulation 4(1) of Principal Regulations

5. The definition of “Directive” in Regulation 4(1) of the Principal Regulations is amended by the addition to it of references to Commission Directives 2009/129/EC, 2009/130/EC, 2009/134/EC, 2009/159/EU, 2009/164/EU and 2010/3/EU and Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008.

Further Amendments

6. Subject to Regulation 3, the Principal Regulations are further amended as provided for in the Schedules.

SCHEDULE 1

Amendment of Principal Regulations to give effect to certain provisions of Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008

1. Regulation 4(1) of the Principal Regulations is amended by the insertion of the following definition after the definition of “Minister”:

“ ‘preparation’ means a mixture or solution composed of two or more substances;”.

2. Regulation 9 of the Principal Regulations is amended—

(a) in paragraphs (2)(a), (2)(b), (4)(a), (4)(b), (5) and (7), by the deletion of “Part 1 or”,

(b) in paragraphs (2)(b) and (4)(b), by the substitution, for “the date”, of “a date”, and

(c) by the substitution, for paragraph (6), of the following paragraph:

“(6) Subject to paragraph (7), a person shall not place on the market any cosmetic product which contains any ingredient or combination of ingredients which has been tested on animals in order to satisfy any requirements of these Regulations or of the Directive no later than the date on which such tests are required to be replaced by one or more validated methods listed in Commission Regulation (EC) No. 440/2008⁸ of 30 May 2008, as amended by Commission Regulation (EC) No. 761/2009⁹ of 23 July 2009, laying down test methods pursuant to Regulation (EC) No. 1907/2006¹⁰ of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or in Part 2 of Schedule 9 to these Regulations.”.

3. Regulation 12 of the Principal Regulations is amended by the substitution, for paragraph (4), of the following paragraph:

“(4) For the purposes of paragraph (3), the quantitative information required under subparagraph (a) of paragraph (1) is limited to substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex 1 to Regulation (EC) No. 1272/2008¹¹:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

⁸OJ No. L142, 31.05.2008, p1

⁹OJ No. L220, 24.8.2009, p1

¹⁰OJ No. L396, 30.12.2006, p1

¹¹OJ No. L353, 31.12.2008, p1

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.”.

3. Schedule 9 to the Principal Regulations is amended—

(a) by the deletion of Part 1, and

(b) by the substitution, for the first sentence of Part 2, of the following sentence:

“This Part lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of the Directive and which are not listed in Regulation (EC) No 440/2008.”.

SCHEDULE 2

Amendment of Principal Regulations to give effect to Commission Directive 2009/129/EC of 9 October 2009

Column f of reference numbers 26 to 43, 47 and 56 in Part 1 of Schedule 3 to the Principal Regulations is amended by the substitution, for the text after the first sentence, of the following text:

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

‘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.’”.

SCHEDULE 3

Amendment of Principal Regulations to give effect to Commission Directive 2009/130/EC of 12 October 2009

Part 1 of Schedule 3 to the Principal Regulations is amended—

(1) in column b of reference number 8, by the substitution, for the existing text, of the following text:

“N-substituted derivatives of p-Phenylenediamine and their salts; N-substituted derivatives of o-Phenylenediamine¹, with the exception of those

derivatives listed elsewhere in this Schedule and under reference numbers 1309, 1311, and 1312 in Schedule 2”,

(2) subject to paragraphs 1(1) and 1(4) of Schedule 4, by the insertion of the following reference number after reference number 8:

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
“8a	<p>p-Phenylenediamine and its salts¹ CAS No 106-50-3 Einecs 203-404-7</p> <p>p-Phenylenediamine HCl CAS No 624-18-0</p> <p>Einecs 210-834-9 p-Phenylenediamine sulphate CAS No 16245-77-5 Einecs 240-357-1</p>	<p>Hair dye substance in oxidative hair dye products</p> <p>(a) general use</p> <p>(b) professional use</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>(a) Can cause an allergic reaction. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows.</p> <p>(b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Wear suitable gloves.”,</p>

(3) in column b of reference number 9, by the substitution, for the existing text, of the following text:

“Methylphenylenediamines, their N-substituted derivatives and their salts¹, with the exception of a substance mentioned in reference number 9a in this Schedule and substances under reference numbers 364, 1310 and 1313 in Schedule 2”,

(4) subject to subparagraphs (3) and (4) of paragraph 1 of Schedule 4, by the insertion of the following reference number after reference number 9:

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
"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) professional use		(a) and (b) After mixing under oxidative conditions, the maximum concentration applied to hair must not exceed 4 % calculated as free base.	As mentioned in reference number 9, column f."

and

(5) in reference number 14, by the deletion—


- (i) in column d, of "0.3%", and
- (ii) in column f, of paragraph (a).

SCHEDULE 4

Amendment of Principal Regulations to give effect to Commission Directive 2009/134/EC of 28 October 2009

1. Part 1 of Schedule 3 to the Principal Regulations is amended—

(1) subject to subparagraph (4), in paragraphs (a) and (b) in column f of reference numbers 8 and 8(a) (inserted by paragraph (2) of Schedule 3), by the substitution, for "Can cause an allergic reaction", of the following text:

“ 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.”,

(2) in column f of reference number 9, by the substitution, for the existing text, of the following text:

“(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,
- you have experienced a reaction to a temporary ‘black henna’ tattoo in the past.

Contains phenylenediamines (toluenediamines).

Wear suitable gloves.”,

(3) subject to subparagraph (4), in column f of reference number 9a (inserted by paragraph (4) of Schedule 3), by the substitution, for the existing text, of the following text:

“(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,
- you have experienced a reaction to a temporary ‘black henna’ tattoo in the past.

Contains phenylenediamines (toluenediamines).

Wear suitable gloves.”,

(4) in paragraphs (a) and (b) in column f of reference numbers 8a and 9a, by the insertion of “The mixing ratio is printed on the label.”,

(5) in column f of reference number 16, by the substitution, for “Can cause allergic reaction.”, of the following text:

 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.”,

(6) in subparagraphs (i) and (ii) of paragraph (a) in column f of reference number 22, by the insertion of the following text:

 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.”,

(7) in paragraph (a) in column f of reference numbers 202 and 203, by the substitution, for “Can cause allergic reaction.” of the following text:

 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.”,

and

(8) in paragraph (a) in column f of reference numbers 193 and 205, by the insertion of the following text:



“ 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.”.

2. Part 2 of Schedule 3 to the Principal Regulations is amended—

(1) in paragraphs (a) and (b) in column f of reference number 3, by the substitution, for “Can cause allergic reaction.”, of the following text:



“ 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.”,

(2) in column f of reference numbers 4, 20, 26, 32, 34 to 39 and 44, by the insertion of the following text:



“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.”,

(3) in column f of reference numbers 5, 6, 12, 19, 21, 22, 25 and 33, by the substitution, for “Can cause allergic reaction.”, of the following text:



“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.”,

(4) in column f of reference numbers 10, 11 and 16—

- (a) by the substitution in paragraph (a), for “Can cause allergic reaction.”, of the following text:



“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.”, and

(b) by the deletion of paragraph (b),

(5) in column f of reference numbers 27, 48 and 56, by the insertion of the following paragraphs:



“(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.”,

and

(6) in paragraph (a) in column f of reference numbers 31, 49, 50 and 55, by the addition of the following text:



“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

Amendment of Principal Regulations to give effect to Commission Directive 2009/159/EU of 16 December 2009

Column g of reference numbers 3 to 6, 10 to 12, 16, 19 to 22, 25 to 27, 29, 31 to 39, 44, 48 to 50, 55 and 56 in Part 2 of Schedule 3 to the Principal Regulations is amended by the substitution, for “31.12.2009”, of “31.12.2010”.

SCHEDULE 6

Amendment of Principal Regulations to give effect to Commission Directive 2009/164/EU of 22 December 2009

1. Reference number 450 in Schedule 2 to the Principal Regulations is amended by the substitution, for the existing text, of the following text:

“Verbena essential oils (*Lippia citriodora* Kunth.) and derivatives other than absolute (CAS No 8024-12-2), when used as a fragrance ingredient.”.

2. Part 1 of Schedule 3 to the Principal Regulations is amended—

(1) in column b of reference number 130, by the substitution, for “Terpene terpenoids sinpine”, of “Terpenes and terpenoids”,

(2) by the insertion, after reference number 151, of the following reference number:

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
"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 %",	

and

(3) by the insertion, after reference number 205, of the following reference number:

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
"206	Verbena absolute (<i>Lippia citriodora</i> Kunth.) CAS No 8024-12-2		0.2 %".		

SCHEDULE 7

Amendment of Principal Regulations to give effect to Commission Directive 2010/3/EU of 1 February 2010

1. Part 1 of Schedule 3 to the Principal Regulations is amended by the insertion, after reference number 206 (inserted by paragraph 2(3) of Schedule 6), of the following reference number and footnote:

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
"207	Ethyl Lauroyl Arginate HCl (INCI) (*) Ethyl-Na-dodecanoyl-L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	(a) soap (b) anti-dandruff shampoos (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.	

(*) For use as a preservative, see reference number 58 in Part 1 of Schedule 6.”.

2. Part 1 of Schedule 6 to the Principal Regulations is amended by the insertion, after reference number 57, of the following reference number and footnote:

Reference number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
"58	Ethyl Lauroyl Arginate HCl (INCI) (O) (**) Ethyl-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.	

(**) For uses other than as a preservative, see reference number 207 in Part 1 of Schedule 3 ”.



GIVEN under my Official Seal,
6 May 2010.

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the European Communities (Cosmetic Products) Regulations 2004 to 2009. They update the law in relation to the manufacture, marketing and sale of cosmetic products by the implementation of Commission Directives 2009/129/EC, 2009/130/EC, 2009/134/EC, 2009/159/EU, 2009/164/EU and 2010/3/EU and Directive 2008/112/EC of the European Parliament and of the Council with a view to improving the safety of those products. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2010.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

€4.06



Wt. (B27618). 285. 5/10. Cahill. Gr. 30-15.