

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,586, 30 ta' April, 2010

Taqsima B

L.N. 245 of 2010

**PRODUCT SAFETY ACT
(CAP. 427)**

Cosmetic Products (Amendment) Regulations, 2010

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Prime Minister has, on the advice of the Malta Standards Authority, made the following regulations:-

1. The title of these regulations is the Cosmetic Products (Amendment) Regulations, 2010, and they shall be read and construed as one with the Cosmetic Products Regulations, 2004, hereinafter referred to as “the principal regulations”.

Citation.
L.N. 424 of 2004.

2. (1) Regulations 3, 4(a) and 8 of these regulations shall apply as from 1st June, 2010 while regulations 4(b) and 5 shall apply as from 1st December, 2010. These regulations implement the provisions of Commission Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Commencement and
scope.

(2) Regulation 7(a)(ix) of these regulations shall apply as from 15 October 2010. This regulation implements the provisions of Commission Directive 2009/129/EC of 9 October 2009 amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress.

(3) Regulations 7(a)(i), 7(a)(iii), section B of 7(a)(iv), 7(a)(v) and 7(a)(vi) of these regulations shall apply as from 15 July 2010. These regulations implement the provisions of Commission Directive 2009/130/EC of 12 October 2009 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress.

(4) After 1st November, 2011, no cosmetic products, which fail to comply with sub-regulations 7(a)(ii), section A of 7(a)(iv), 7(a)(vii), 7(a)(viii), 7(a)(xii), 7(a)(xiii) and 7(b)(i) to 7(b)(vi) of these regulations should be placed on the market. The conditions of use and warnings which must be printed on the label,

under column f, established in sub-regulations 7(a)(iii) and 7(a)(v) of these regulations, should also apply as from 1st November, 2011. After 1st November, 2012, no cosmetic products which fail to comply with these regulations should be sold or disposed of to the final consumer. These regulations implement the provisions of Commission Directive 2009/134/EC of 28 October 2009 amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress.

(5) Regulations 6, 7(a)(x), 7(a)(xi) and 7(a)(xiv) of these regulations shall apply as from 15 February 2011. These regulations implement the provisions of Commission Directive 2009/164/EU of 22 December 2009 amending, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC concerning cosmetic products.

(6) Regulation 7(b)(vii) of these regulations shall be deemed to have come into force on the 1st of January 2010. These regulations implement the provisions of Commission Directive 2009/159/EU of 16 December 2009 amending, for the purpose of adaptation to technical progress, Annex III to Council Directive 76/768/EEC concerning cosmetic products.

General amendment
to the principal
regulations.

3. For the words “preparation” or “preparations”, wherever they occur in the principal regulations, there shall be substituted the words “mixture” or “mixtures” respectively.

Amends regulation
5 of the principal
regulations.

4. Regulation 5 of the principal regulations shall be amended as follows:

(a) in sub-regulation 5.3, paragraph (d) shall be substituted with the following:

“(d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this regulation, 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 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or in the Tenth Schedule to their regulations.”; and

(b) immediately after sub-regulation 5.4, there shall be added the following new sub-regulation:

“5.5 The use in cosmetic products of substances classified as carcinogenic, germ cell mutagenic or toxic for reproduction, of category 1A, 1B and 2, under part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures shall be prohibited. A substance classified in category 2 may be used in cosmetics if the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found acceptable for use in cosmetic products.”.

5. In regulation 7.1, in proviso 7.1.2 thereof, for the words from “The quantitative information” to the words “Directive 67/548/EEC” there shall be substituted the following:

Amends regulation 7 of the principal regulations.

“ 7.1.2. The quantitative information required under paragraph (a) to be made publicly accessible shall be limited to substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (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;
- (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.”.

6. In the Second Schedule to the principal regulations reference number 450, “Verbena oil (*Lippia citriodora* Kunth.) (CAS No 8024-12-2), when used as a fragrance ingredient” shall be substituted by “Verbena essential oils (*Lippia citriodora* Kunth.) and derivatives other than absolute (CAS No 8024-12-2), when used as a fragrance ingredient.”.

Amends the Second Schedule to the principal regulations.

7. The Third Schedule to the principal regulations shall be amended as follows:

Amends the Third Schedule to the principal regulations.

(a) in Part I thereof –

(i) in column ‘b’ of reference number 8, the words “p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine, with the exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II” there shall be substituted the following:

“N-substituted derivatives of p-Phenylenediamine and their salts; N-substituted derivatives of o-Phenylenediamine ⁽¹⁾, with exception of those derivatives listed elsewhere in this Schedule and under reference numbers 1309, 1311, and 1312 in the Second Schedule.”;

(ii) under reference number 8, in column f, for the words “Can cause an allergic reaction” there shall be substituted the following:



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.”;

(iii) the following reference number 8a shall be inserted immediately 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 salts (⁵)</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>Hair dye substance in oxidative hair dye products</p> <p>(a) general use</p> <p>(b) professional use</p>		<p>(a) and (b)</p> <p>After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % calculated as free base.</p>	<p>(a)</p>  <p>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</p>

¹ These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1.

	<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>of allergy.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> — 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. <p>Contains phenylenediamines. Do not use to dye eyelashes or eyebrows.</p> <p>The mixing ratio is printed on the label.</p> <p>(b) For professional use only. Contains phenylenediamines.</p>  <p>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.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> — 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. <p>Wear suitable gloves.</p> <p>The mixing ratio is printed on the label.”;</p>
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(iv) under reference number 9,

A. for the words “(a) (b) Can cause allergic reaction” in column f, there shall be substituted the following:

“(a)



Hair colorants can cause severe allergic reactions.

Read and follow instructions.

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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.”.

B. in column ‘b’ of reference number 9, for the words “Methylphenylenediamines, their N-substituted derivatives and their salts with the exception of substances under reference numbers 364, 1310 and 1313 in Annex II” there shall be substituted the following:

“Methylphenylenediamines, their N-substituted derivatives and their salts ⁽²⁾, with the exception of the substance under reference number 9a in this Schedule and substances under reference numbers 364, 1310 and 1313 in the Second Schedule.”;

(v) the following reference number 9a shall be inserted immediately 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	<p>Toluene-2,5-diamine and its salts ⁽¹⁾</p> <p>CAS No 95-70-5</p> <p>Einecs 202-442-1</p> <p>Toluene-2,5-diamine sulphate</p> <p>CAS No 615-50-9</p> <p>Einecs 210-431-8</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)</p> <p>After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 4% calculated as free base.</p>	<p>(a)</p>  <p>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.</p> <p>The mixing ratio is printed on the label.</p> <p>(b) For professional use only.</p>  <p>Hair colorants can cause severe allergic reactions.</p>

² These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.

					<p>Read and follow instructions. This product is not intended for use on persons under the age of 16.</p> <p>Temporary “black henna” tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> — 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. <p>Contains phenylenediamines (toluenediamines). Wear suitable gloves.</p> <p>The mixing ratio is printed on the label.”;</p>
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(vi) in reference number 14, the following shall be deleted:

- (i) the maximum authorised concentration in the finished cosmetic product of 0.3 % in column ‘d’; and
- (ii) paragraph (a) in column ‘f’;

(vii) under reference number 16, in column f, for the words “(a)(b) Can cause allergic reaction” there shall be substituted the following:

“



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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.”;

- (viii) under reference number 22, in column f, sub-points 1 and 2 of point (a), the following text is added:

“



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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.”;

- (ix) in column ‘f’, corresponding to reference numbers 26 to 43, 47 and 56, the words “For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contraindicated 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 minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.”.” there shall be substituted the following:

“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.”.”;

- (x) in column ‘b’ of the entry relating to reference number 130, the words “Terpene terpenoids sinpine” shall be substituted with “Terpenes and terpenoids”;

(xi) the following shall be inserted immediately after the entry with reference number 151:

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 %";	

(xii) under reference numbers 193 and 205, in column f, point (a), the following text is added:

"



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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.";

- (xiii) under reference numbers 202 and 203, in column f, point (a), the text “Can cause allergic reaction.” is substituted with the following:

“



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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.”;

- (xiv) the following entry is added after reference number 205:

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 %”.		

(b) In Part II thereof:

- (i) under reference number 3 in column f, the text “(a) (b) Can cause allergic reaction” there shall be substituted the following:

“



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.”;

- (ii) under reference numbers 4, 20, 26, 32, 34, 35, 36, 37, 38, 39 and 44, column f, the following text is added:

“



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.”;

(iii) under reference numbers 5, 6, 12, 19, 21, 22, 25 and 33, in column f, the text “Can cause allergic reaction.” is substituted with the following:

“



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.”;

(iv) under reference numbers 10, 11 and 16:

A. in column f, the text “(a) Can cause allergic reaction” there shall be substituted the following:

“



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. column f, point (b) is deleted;

- (v) under reference numbers 27, 48 and 56, in column f, the following points (a) and (b) are added:

“(a)



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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)



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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.”;

(vi) under reference numbers 31, 49, 50 and 55, in column f, point (a), the following text is added:

“



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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

(vii) in reference numbers 3, 4, 5, 6, 10, 11, 12, 16, 19, 20, 21, 22, 25, 26, 27, 29, 31, 32, 33, 34, 35, 36, 37, 38, 39, 44, 48, 49, 50, 55, and 56 of column g, the date “31.12.2009” shall be substituted with “31.12.2010”.

8. In the Tenth Schedule to the principal regulations for the words from “This Schedule lists” to the words “ of dangerous substances.” there shall be substituted the words:

Amends the Tenth
Schedule to the
principal regulations.

“This Schedule 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 this Regulation and which are not listed in Regulation (EC) No 440/2008.”.

VERŻJONI ELETTRONIKA

