

Awtorita' Maltija dwar I-iStandards
It-Tieni Sular, Binja Evans
Triq Merkanti
Valletta VLT1179
Malta

Tel: (+356) 29 492 000
Fax: (+356) 21 242 406
Email: info@msa.org.mt
URL: www.msa.org.mt
Reg. No.: MT 1515-0502

Chairman: Ing. Francis E. Farrugia



Malta Standards Authority
Second Floor, Evans Building
Merchants Street
Valletta VLT1179
Malta



Certificate No.
FS 80769
MSA EN ISO 9001:2000

Our Ref: ICDC 2009_08

The Cosmetic Products (Amendment) Regulations, 2010

The Cosmetic Products Regulations needs to be amended due to the publication of the following 4 directives:

1. [DIRECTIVE 2008/112/EC](#) 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.

[Regulation \(EC\) No 1272/2008](#) on classification, labelling and packaging of substances and mixtures (CLP Regulation) provides for the harmonisation of the classification and labelling of substances and mixtures within the Community. That Regulation will replace Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances as well as Directive 1999/45/EC concerning the classification, packaging and labelling of dangerous preparations.

Regulation (EC) No 1272/2008 builds on the experience with Directives 67/548/EEC and 1999/45/EC and incorporates the criteria for classification and labelling of substances and mixtures provided for by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which has been adopted at the international level, within the structure of the United Nations.

Certain provisions on classification and labelling laid down in Directives 67/548/EEC and 1999/45/EC also serve for the purpose of application of other Community legislation, such as Council Directive 76/768/EEC relating to cosmetic products. The incorporation of the GHS criteria into Community legislation leads to the introduction of new hazard classes and categories only partially corresponding to the classification and labelling arrangements provided for by Directives 67/548/EEC and 1999/45/EC.

An analysis of the potential effects of the transition from the old to the new system of classification and labelling has led to the conclusion that, by adapting the references to the classification criteria in Directives affected, including that of cosmetics, to the new system introduced by Regulation (EC) No 1272/2008, the scope of the respective acts should be maintained.

It is also necessary to adapt the Cosmetics Directive to take into account the adoption of REACH Regulation.

The transition from the criteria for classification contained in Directives 67/548/EEC and 1999/45/EC should be fully completed on 1 June 2015. Cosmetic manufacturers, importers or downstream users

within the meaning of the CLP Regulation should be enabled to design their transition strategy under this Directive (2008/112/EC) in a similar timeframe as under the CLP Regulation.

2. [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

The compounds containing fluorine are currently regulated under reference numbers 26 to 43, and reference numbers 47 and 56 in Part 1 of Annex III to Directive 76/768/EEC. Their maximum authorised concentration in toothpastes refers to the content of elemental fluorine (0.15% calculated as F, i.e. 1500 ppm).

The Scientific Committee on Consumer Safety (SCCS) stated in its opinion SCCP/0882/08 that the maximum permitted concentration of 0.15 % (1500 F - ppm) fluoride does not pose a safety concern when used by children under the age of six years, based on the available scientific evidence. The data used were generated from studies primarily on sodium fluoride. Based on the scientific conclusions of the SCCS, [Commission Directive 2007/53/EC](#) introduced for the regulated compounds containing fluorine a requirement for warning which must be printed on the label of toothpastes containing fluoride. This requirement refers to the content of fluoride instead of elemental fluorine. As a result, not all fluorine containing compounds listed in Part 1 of Annex III to Directive 76/768/EEC were covered by the introduced labelling requirement. Upon request of the Commission, the SCCS clarified that in opinions SCCNFP/0653/03 and SCCP/0882/05, it was pointed out that an extrapolation to other compounds containing fluorine listed in Part 1 of Annex III to Directive 76/768/EEC could only be made with respect to fluorosis. However, for the purpose of the reference to compounds containing fluorine in Part 1 of Annex III to Directive 76/768/EEC, introduced by Directive 2007/53/EC, the SCCS considered that the terms 'fluorine' and 'fluoride' were equivalent and interchangeable.

To ensure legal certainty, it is necessary to clarify that the labelling requirement refers to all 20 compounds containing fluorine listed in Part 1 of Annex III to Directive 76/768/EEC, and not only to those containing fluoride. Therefore, the condition for labelling which must be printed on the label of toothpastes containing fluorine compounds listed in Part 1 of Annex III to Directive 76/768/EEC should refer to the content of fluorine instead of fluoride.

3. [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

Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the SCCS concluded that the potential risks were of concern. It recommended that the Commission take further steps to control the use of hair dye substances. The SCCS further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity/mutagenicity.

Substances p-Phenylenediamine (PPD) and toluene-2,5-diamine (PTD) are currently regulated under generic entries 8 and 9 in part 1 of Annex III to Council Directive 76/768/EEC. The SCCS classified these substances as extreme sensitizers contributing to a great extent to the incidence of skin allergies among consumers to hair dye products. The risk assessment of the submitted additional data on PPD and PTD, and final decisions made by the SCCS on the safety of these substances might still require a considerable amount of time. As a precautionary measure to reduce the risk of allergies to hair dye products among consumers, the maximum authorised concentrations of PPD and PTD should be immediately decreased to the levels for which the industry submitted the safety files.

[Commission Directive 2008/88/EC](#) banned the use of hydroquinone in oxidative hair dye products by deleting the respective field of application in column 'c' of reference number 14 in Annex III, part 1. For the sake of clarity, the authorised concentration of 0.3 % in column 'd' and the conditions of use and warnings which must be printed on the label listed in paragraph (a) in column 'f' of reference number 14 should be deleted as well.

4. [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

The SCCS concluded in its 'Memorandum on hair dye substances and their skin sensitising properties' published on 29 March 2007 that contact allergies caused by hair dye products are an increasingly important health problem for consumers and society, often causing acute and severe dermatitis to individuals. A person sensitised to a hair dye substance used in hair dye products may eventually develop skin allergy to that substance. In order to better inform the consumer about the possible adverse effects of hair colouring and to lower the risk of sensitisation to hair dye products among consumers, additional warnings should be printed on the label of oxidative hair dye products and of certain non-oxidative hair dye products containing extreme and strong sensitising substances. Therefore, the obligatory conditions of use and warnings laid down for respective hair dye substances in column 'f' of Annex III to Directive 76/768/EEC should be amended.



These four Directives were thus transposed in the proposed regulations:

The Cosmetic Products (Amendment) Regulations, 2010 -

Chairman, MSA

Minister of Finance, the Economy and Investment

L.N. of 2010

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

The Cosmetic Products (Amendment) Regulations, 2010

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

Citation.

L.N. 424 of 2004.

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”.

Commencement and scope.

2. (1) Regulations 3, 4(1) and 7 shall apply as from 1st June, 2010 while regulations 4(2) 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.

(2) Regulation 6(1)(a) 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) Sub-regulations 6(1)(b) to (f) 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 6(1)(g) to (l) and 6(2), 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 6(1)(c) and (e), 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.

Amends the principal regulations.

3. The word “preparation” or “preparations”, within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be substituted by “mixture” or “mixtures” respectively throughout the text of the principal regulations.

Amends the Fifth Regulation to the principal regulations.

4. (1) In regulation 5.3, point 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 this Regulation.”

- (2) The following regulation shall be added after regulation 5.4:

“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.”

Amends the Seventh Regulation to the principal regulations.

5. In regulation 7.1, the last sentence of the second sub-paragraph of point (h) shall be replaced by the following:

“The quantitative information required under (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.”.

Amends the Third Schedule to the principal regulations.

6. (1) Part 1 of the Third Schedule is amended as follows:

a. 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.”.” shall be substituted with 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.”.”

b. 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” are replaced by 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.”.

c. The following reference number 8a shall be inserted 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	Other limitations and requirements	

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.

			product		
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>Einecs 210-834-9</p> <p>p-Phenylenediamine sulphate</p> <p>CAS No 16245-77-5</p> <p>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)</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 of allergy. 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. 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.

					Wear suitable gloves. The mixing ratio is printed on the label.”.
--	--	--	--	--	--

- d. In column ‘b’ of reference number 9, 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” are replaced by 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.”.

- e. The following reference number 9a shall be inserted 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.	(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. The mixing ratio is printed on

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>the label.</p> <p>(b) For professional use only.</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). Wear suitable gloves.</p> <p>The mixing ratio is printed on the label.”.</p>
--	--	--	--	---

- f. For Part 1 of the Third Schedule, 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’.
- g. Under reference number 8, in column f, points (a) and (b), the text “Can cause an 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.”

h. Under reference number 9, the text in column f is substituted with the following:

“(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.”.

i. Under reference number 16, 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.”.

- j. Under reference number 22, in column f, sub-points 1 and 2 of point (a), 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.”.

- k. Under reference numbers 202 and 203, in column f, point (a), 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.”.

1. Under reference numbers 193 and 205, in column f, point (a), 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.”.

- (2) Part 2 of the Third Schedule is amended as follows:

- (a) Under reference number 3 in column f, points (a) and (b), 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.”.

(b) 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.”.

(c) 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.”.

(e) Under reference numbers 10, 11 and 16, in column f, point (a), 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.”

(e) Under reference numbers 10, 11 and 16, column f, point (b) is deleted.

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

“(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.”.

(g) Under reference numbers 31, 49, 50 and 55, in column f, point (a), 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.”

Amends the Tenth Schedule to the principal regulations.

7. (1) In the Tenth Schedule, the first sentence shall be replaced by the following:

“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.”.

The MSA's web page on Cosmetics may be found at:

<http://www.msa.org.mt/rad/cosmetics/index.htm>

The European Commission's website on Cosmetics may be found at:

http://ec.europa.eu/enterprise/cosmetics/index_en.htm

Your comments on the proposed Regulations are invited. Note that this information document does not seek your views on the Directives but on the proposed regulations for implementing it.

*Any comments should reach the Directorate in writing or via email by **Tuesday 22nd December, 2009.***

For any other information kindly contact the Regulatory Affairs Directorate of the Malta Standards Authority using the following contact details:

Malta Standards Authority
(Attn: Head - Regulatory Affairs Directorate)
Second Floor, Evans Building, Merchants Street, Valletta, VLT1179

Tel no: +(356) 23952000

Fax no: +(356) 21242406

Email: consultations.msa@msa.org.mt

