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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM

Draft

COMMISSION DIRECTIVE/.../EC

of [...]

**amending Council Directive 76/768/EEC concerning cosmetic products for the purposes
of adapting Annex III thereto to technical progress**

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amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

- (1) The Scientific Committee on Consumer Products, replaced by the Scientific Committee on Consumer Safety², concluded in its “Memorandum on hair dye substances and their skin sensitizing 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.
- (2) In order to better inform the consumer about the possible adverse effects of hair colouring and to lower the risk of sensitization 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 sensitizing 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.
- (3) Directive 76/768/EEC should therefore be amended accordingly.
- (4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

¹ OJ L 262, 27.9.1976, p. 169.

² The name of the committee was changed by Commission Decision 2008/721/EC (OJ L 241, 10.9.2008, p. 21).

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by **[insert concrete date = 6 months after the entry into force of the Directive]** at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

Member States shall take all necessary measures to ensure that after **[Day, Month, Year = 24 months after the entry into force of the Directive]** no cosmetic products which fail to comply with this Directive are placed on the market by Community manufacturers or by importers established within the Community.

Member States shall take all necessary measures to ensure that after **[Day, Month, Year = 36 months after the entry into force of the Directive]** no cosmetic products which fail to comply with this Directive are sold or disposed of to the final consumer in the Community.

Article 4

This Directive shall enter into force on the **twentieth** day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX

1. Part 1 of Annex III is amended as follows:

(a) Under reference numbers 8 and 9, in column f, points (a) and (b), the text “Can cause an allergic reaction.” is replaced by 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 8a and 9a, in column f, points (a) and (b), the text “Can cause an allergic reaction.” is replaced by 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.”

(c) Under reference number 16, in column f, the text "Can cause allergic reaction." is replaced by the following:

“



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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.”

(d) 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.”

(e) Under reference numbers 202 and 203, in column f, point (a), the text “Can cause allergic reaction.” is replaced by 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.”

(f) 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.”

2. Part 2 of Annex III is amended as follows:

(a) Under reference numbers 3 in column f, points (a) and (b), the text “Can cause allergic reaction.” is replaced by 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 replaced by 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.”

(d) Under reference numbers 10, 11 and 16, in column f, point (a), the text “Can cause allergic reaction.” is replaced by 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)



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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)



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.”