

**GUIDANCE NOTE: THE RESTRICTION TO “PROFESSIONAL USE” IN THE COSMETICS
DIRECTIVE 76/768/EEC**

VERSION 1.0 (DECEMBER 2005)

PLEASE NOTE: THIS DOCUMENT PROVIDES GUIDANCE AS TO THE MEANING OF THE RESTRICTION TO PROFESSIONAL USE IN THE COSMETICS DIRECTIVE 76/768.

TO DEVELOP THIS GUIDANCE NOTE THE COMMISSION SET UP A SUB-WORKING GROUP COMPOSED OF REPRESENTATIVES OF MEMBER STATES AND STAKEHOLDERS. THE SUB-WORKING GROUP PRESENTED ITS CONCLUSIONS TO THE WORKING GROUP ON COSMETIC PRODUCTS ON 8 DECEMBER 2005. THIS GROUP IS CHAIRED BY THE COMMISSION AND IS COMPOSED OF REPRESENTATIVES OF ALL MEMBER STATES, OF EU AND EFTA, BEUC, THE EUROPEAN ORGANISATION OF CONSUMERS, COLIPA, EUROPEAN FEDERATION OF COSMETIC PRODUCTS, EFFCI, EUROPEAN FEDERATION FOR COSMETIC INGREDIENTS, EFFA, EUROPEAN FLAVOUR AND FRAGRANCES ASSOCIATION AND UNITIS, EUROPEAN ORGANISATION OF COSMETIC INGREDIENTS INDUSTRIES AND SERVICES. A GENERAL CONSENSUS WAS REACHED ON THESE GUIDELINES.

PLEASE NOTE ALSO THAT THIS GUIDANCE NOTE ADDRESSES THE CONCEPT OF “RESTRICTION TO PROFESSIONAL USE” AS USED IN THE ANNEXES TO THE COSMETICS DIRECTIVE AT THE DATE OF THIS DOCUMENT. OBVIOUSLY, THESE VIEWS MAY EVOLVE AND CHANGE IN THE LIGHT OF FUTURE DEVELOPMENTS AND THIS GUIDANCE NOTE MAY BE ADAPTED ACCORDINGLY.

THE VIEWS EXPRESSED IN THIS GUIDANCE NOTE ARE NOT LEGALLY BINDING; ONLY THE EUROPEAN COURT OF JUSTICE (“COURT”) CAN GIVE AN AUTHORITATIVE INTERPRETATION OF COMMUNITY LAW.

1. BACKGROUND

1. Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (“**Cosmetics Directive**”) provides in Article 4 that “[...] Member States shall prohibit the marketing of cosmetic products containing [...] substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down”.
2. A number of substances listed in annex III contain in the section “restrictions” the entry “professional use”, which is listed either in column ‘c’ (“field of application and/or use”¹) or in column ‘e’ (“other limitations and requirements”²). A list of all substances subject to professional use is annexed to this note.

¹ Ref.-no. 2a, 2b, 8, 9, 10, 14, 15a, 15b, 22, 64 of annex III. Note, however, that these entries are not necessarily linked to Art. 6 (1) d 1st sentence, 2nd part. Rather, this provision concerns additional

3. For the purpose of this document these entries shall be termed “restriction to professional use”.
4. The restriction to professional use is complemented in column f (“conditions of use and warnings which must be printed on the label”) with the wording “for professional use only”.³
5. The restriction to professional use stems in some cases from the fact that industry, when submitting the safety dossier, asks for evaluation of this ingredient exclusively for the use by professionals, such as hairdressers.⁴
6. This guidance note attempts to provide guidance as to the meaning of the restriction to professional use. Its content has been the result of intensive discussion with representatives of Member States and representatives of industry.
7. In some cases products may also be marketed as “products only for professionals”, “professional products”, “professional line” etc. as part of a marketing strategy, without a regulatory obligation to this restriction in the Cosmetics Directive. This guidance note does not address restrictions based on marketing considerations but addresses only the restriction to professional use as a regulatory obligation stemming from the Cosmetics Directive.

2. THE PURPOSE OF THE RESTRICTION TO PROFESSIONAL USE

8. The main objective of the Cosmetics Directive is safeguarding public health while ensuring the free market for cosmetic products.⁵
9. In order to attain this objective the Cosmetics Directive exhaustively⁶ harmonises the labelling provisions for products placed on the Community market. The Cosmetics

“precautionary information on cosmetic products for professional use, in particular in hairdressing” which may need to be labelled on products for professional use (cf. ECJ, Case C-169/99 *Schwarzkopf*, of 13.9.2001, ECR 2001 I-5901, paras 29-30).

² Such as ref. no. 94, 95 of annex III.

³ One exception is reference no. 3 (Oxalic acid, its esters and alkaline salts), where “professional use” is referred to only in the column “Conditions of use and warnings which must be printed on the label”.

⁴ Cf. for example, the opinion on strontium peroxide, adopted by the scientific committee in its plenary session of 7 October 1992, in the plenary meeting of 25 June 1993, and in the plenary meeting of 10 December 1993. More recently, cf. the opinion on Benzoyl Peroxide and Hydroquinon (SCCNFP/0486/01).

⁵ Cf. Cosmetics Directive, recitals 2-4.

⁶ The European Court of Justice has ruled on various occasions that the Cosmetics Directive “*provides exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products*” and that Member States are hindered to adopt additional rules in this respect (Case C-220/98 *Lifting* [2000] ECR I-117, paragraph 23; Cf. also Case C-150/88 *Parfümerie-Fabrik 4711 v Provide* [1989] ECR 3891, paragraph 28; Case C-315/92 *Verband Sozialer Wettbewerb v Clinique Laboratories and Estée Lauder* [1994] ECR I-317, paragraph 11).

Directive also regulates ingredients of cosmetic products through banning, restricting or authorising.

10. The restriction to professional use contributes to this objective⁷; it ensures that products which:

- contain certain substances⁸ or
 - contain substances in a higher concentration than for general use⁹ or
 - do not contain certain warnings which are obligatory when used by the consumer¹⁰
- are used by a professional only.

11. A professional is generally assumed to have a certain degree of professional education and/or professional experience. In particular, a professional usually:

- is more familiar with the risks for health of a specific substance or its concentration in a cosmetic product than a consumer;
- has more expertise (eg professional expertise) in applying cosmetic products correctly on the consumer – this is in particular the case for substances which are used on the nails or on the hair but which must not get in contact with the skin; and
- disposes of more information on the product/its ingredients.

Finally, it is usually easier to inform professional users than the general public about the correct use of a cosmetic product.

12. For the sake of completeness, it shall be mentioned here that some substances restricted to professional use also have to bear warnings that aim at protecting the professional.¹¹ The principal aim of the Cosmetics Directive is the safeguarding of

⁷ In this respect, the restriction to professional use can be considered as a ‘concretisation’ of Art. 2 Cosmetics Directive which sets out the basic principle that “a cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling [and] any instructions for its use [...]” (emphasis added).

⁸ Cf. annex III, ref.-no. 3, 64, 94, 95.

⁹ Cf. annex III, ref.-no. 2a, 2b, 15a, 15b.

¹⁰ Cf. annex III, ref.-no. 8, 9, 10, 14, 22.

¹¹ Cf. annex III, ref.-no. 10 and 64 (“wear suitable gloves”). In this respect, cf. the opinion of the scientific opinion on glyceryl monothioglycolate, where the scientific committee stated in its conclusion: “Better occupational hygiene precautions should help to reduce the incidence of hypersensitivity to the compound in hairdressers. Hairdressers need to be instructed to handle this type of permanent wave with greater care and follow the directions already in legal force. Direct skin contact should be avoided. Gloves and improved handling technique may lead to a decrease in the frequency of sensitization.” (opinion adopted at the plenary meeting of 9 March 1994).

human health, no matter if the final product is applied by the consumer or by a professional. However, the *restriction* of a product to professional use does not have as its purpose to *protect* the health of the professional. The warnings aiming at protecting the professional are a *consequence*, not a *cause* for the restriction to professional use.

3. THE MEANING OF THE RESTRICTION TO PROFESSIONAL USE

13. The Cosmetics Directive does not define the terms “professional use” means¹²; nor has the case-law of the European Court of Justice addressed this issue in relation to the Cosmetics Directive¹³ or in relation to other Community legislation.
14. In the light of the purpose and wording of the restriction to professional use a “professional” is **any person who, in exercising his/her professional activity, utilises cosmetic products.**
15. Moreover, the wording “for professional use”¹⁴ indicates that the restriction extends to the *use* of the product: thus, **the cosmetic product has to be used, eg. applied, and not merely sold, by a professional.**
16. This definition applies no matter if the restriction to professional use is listed in column ‘c’, ‘e’ or ‘f’ of Annex III.

4. ENFORCING THE RESTRICTION TO PROFESSIONAL USE

17. A Directive, such as the Cosmetics Directive, is binding only as to the result to be achieved, but leaves to the national authorities the choice of form and methods.¹⁵ In transposing and applying the Cosmetics Directive and the restriction to professional use, national authorities are free to choose the forms and methods in order to ensure that the final result (here: the product is only used by professionals) is achieved.
18. These forms and methods might include:
 - National rules providing that the products containing the ingredients in question may only be used by a professional;
 - National rules providing that products containing the ingredients in question must only be sold to professionals for their own use.

¹² It shall be mentioned here that a number of other legislation act of the Community refer to „professional use“, such as in the biocidal products Directive 1998/8, and the General products safety Directive 2001/95. However, in neither of these Directives the term is defined.

¹³ Note, however, that the ECJ has discussed the restriction to professional use *obiter dicta* in Case C-169/99 *Schwarzkopf*, of 13.9.2001, ECR 2001 I-5901, paras 29-30. This case, however, concerned the question how the warnings for professionals, which are contained on products restricted to professional use, are to be labelled according to Art. 7 (1) d 1st sentence of the Cosmetics Directive.

¹⁴ FR: *usage professionnel*; DE: *gewerbliche Verwendung*

¹⁵ Treaty establishing the European Community, Art. 249 (3).

19. The restriction to professional use is unlikely to be achieved if the product is merely labelled accordingly and available to the general public, including consumers in retail shops.

5. THE IMPACT OF THE RESTRICTION TO PROFESSIONAL USE ON THE DISTRIBUTION OF COSMETIC PRODUCTS

20. The Cosmetics Directive **does not directly address the distribution**¹⁶ of cosmetic products within the Community. In this respect, the Cosmetics Directive is similar to 'New Approach' Directives which, in general, do not include provisions regarding distribution.¹⁷ This is also why, as far as obligations for distributors are concerned, the General Product Safety Directive (EC) 2001/95 applies.¹⁸

21. However, the above shows that – depending on the forms and methods Member States apply to achieve the result - the transposition of the Cosmetics Directive may have an **indirect effect on the distribution** of a cosmetic product in the Community: This may be the case, for example, if a Member State chooses to achieve the result by prohibiting the sale of products restricted to professional use in retail shops.

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¹⁶ The terms “distribution” is not defined in the Cosmetics Directive. For the purpose of these guidelines, however, distribution shall be defined as the supply of a cosmetics product subsequently to its placing on the Community market (cf. Guide to the implementation of directives based on the New Approach and the Global Approach, p. 23, under:
http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf)

¹⁷ “Guide to the implementation of Directives based on the New Approach and the Global Approach”, p. 23

¹⁸ Cf. Article 5 (2), (3), (4) General Product Safety Directive 2001/95. See also the “Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety” for more details
(http://pharmacos.eudra.org/F3/cosmetic/cosm_borderline_docs.htm)

**ANNEX: SUBSTANCES RESTRICTED TO PROFESSIONAL USE ACCORDING TO COSMETICS
DIRECTIVE 76/768**

Annex, Reference no.	Substance
III, 2a	Thioglycollic acid and its salts ¹⁹ (if between 8% and 11% ready for use, pH 7 to 9,5)
III, 2b	Thioglycollic acid esters ²⁰ (if between 8% and 11% ready for use, pH 6 to 9,5)
III, 3	Oxalic acid, its esters and alkaline salts ²¹
III, 8	m- and p-Phenylenediamines, their N-substituted derivatives and their salts; Nsubstituted derivatives of o-Phenylenediamines ²² , with the exception of those derivatives listed elsewhere in this Annex (if label does not contain the warning set out in column f litt (a) 1.)
III, 9	Methylphenylenediamines, their N-substituted derivatives and their salts ²³ , with the exception of substance No 364 in Annex II (if label does not contain the warning set out in column f litt (a) 1.)
III, 10	Diaminophenols ²⁴ (if label does not contain the warning set out in column f litt (a) 1.)
III, 14	Hydroquinone ²⁵ (if label does not contain the warning set out in column f litt (a) 1.) Hydroquinone when used as artificial nail systems.
III, 15a	Potassim or sodium hydroxide ²⁶ (if with between 2% and 4,5% by weight).

¹⁹ When used in hair waving and straightening products.

²⁰ When used in hair waving and straightening products.

²¹ Restricted to gair care products.

²² Restricted to oxidizing colouring agents for hair dyeing.

²³ Restricted to oxidizing colouring agents for hair dyeing.

²⁴ Restricted to oxidizing colouring agents for hair dyeing.

²⁵ When used in oxidizing colouring agents for hair dyeing.

²⁶ When used in hair straighteners.

III, 15b	Lithium hydroxide ²⁷ (if with between 1,2% and 4,5% by weight
III, 22	Resorcinol ²⁸ (if label does not contain the warning set out in column f litt. (a) 1).
III, 64	Strontium Peroxide ²⁹
III, 94	Benzoyl peroxide ³⁰
III, 95	Hydroquinone methylether ³¹

²⁷ When used in hair straighteners.

²⁸ When used in oxidizing colouring agents for hair dyeing.

²⁹ Restricted to rinse-off hair care preparations.

³⁰ Restricted to artificial nail systems.

³¹ Restricted to artificial nail systems.