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COUNCIL DIRECTIVE
of 27 July 1976
on the approximation of the laws of the Member States relating to cosmetic products

(76/768/EEC)

(OJ No L 262, 27. 9. 1976, p. 169)

Amended by:

	Official Journal		
	No	page	date
Council Directive of 24 July 1979 (79/661/EEC)	L 192	35	31. 7. 1979
Commission Directive of 11 February 1982 (82/147/EEC)	L 63	26	6. 3. 1982
Council Directive of 17 May 1982 (82/368/EEC)	L 167	1	15. 6. 1982
Second Commission Directive of 30 March 1983 (83/191/EEC)	L 109	25	26. 4. 1983
Third Commission Directive of 29 June 1983 (83/341/EEC)	L 188	15	13. 7. 1983
Fourth Commission Directive of 22 September 1983 (83/496/EEC)	L 275	20	8. 10. 1983
Council Directive of 26 October 1983 (83/574/EEC)	L 332	38	28. 11. 1983
Fifth Commission Directive of 18 July 1984 (84/415/EEC)	L 228	31	25. 8. 1984
Sixth Commission Directive of 16 July 1985 (85/391/EEC)	L 224	40	22. 8. 1985
Seventh Commission Directive of 28 February 1986 (86/179/EEC)	L 138	40	24. 5. 1986
Eighth Commission Directive of 26 March 1986 (86/199/EEC)	L 149	38	3. 6. 1986
Ninth Commission Directive of 2 February 1987 (87/137/EEC)	L 56	20	26. 2. 1987
Tenth Commission Directive of 2 March 1988 (88/233/EEC)	L 105	11	26. 4. 1988
Council Directive of 21 December 1988 (88/667/EEC)	L 382	46	31. 12. 1988
Eleventh Commission Directive of 21 February 1989 (89/174/EEC)	L 64	10	8. 3. 1989
Council Directive of 21 December 1989 (89/679/EEC)	L 398	25	30. 12. 1989
Twelfth Commission Directive of 20 February 1990 (90/121/EEC)	L 71	40	17. 3. 1990
Thirteenth Commission Directive of 12 March 1991 (91/184/EEC)	L 91	59	12. 4. 1991
Fourteenth Commission Directive of 18 February 1992 (92/8/EEC)	L 70	23	17. 3. 1992
Fifteenth Commission Directive of 21 October 1992 (92/86/EEC)	L 325	18	11. 11. 1992
Council Directive of 14 June 1993 (93/35/EEC)	L 151	32	23. 6. 1993
Sixteenth Commission Directive of 22 June 1993 (93/47/EEC)	L 203	24	13. 8. 1993
Seventeenth Commission Directive of 29 June 1994 (94/32/EC)	L 181	31	15. 7. 1994
18th Commission Directive of 10 July 1995 (95/34/EC)	L 167	19	18. 7. 1995
Nineteenth Commission Directive of 25 June 1996 (96/41/EC)	L 198	36	8. 8. 1996

20th Commission Directive of 10 January 1997 (97/1/EC)	L 16	85	18. 1. 1997
Commission Directive of 17 April 1997 (97/18/EC)	L 114	43	1. 5. 1997
21st Commission Directive of 14 July 1997 (97/45/EC)	L 196	77	24. 7. 1997

Twenty-second Commission Directive of 5 March 1998 (98/16/EC)	L 77	44	14. 3. 1998
23rd Commission Directive of 3 September 1998 (98/62/EC)	L 253	20	15. 9. 1998

Amended by:

A1 Act of Accession of Greece	L 291	108	19. 11. 1979
A2 Act of Accession of Spain and Portugal	L 302	218	15. 11. 1985

Corrected by:

- C1 Corrigendum, OJ No L 255, 25. 9. 1984, p. 28 (84/415/EEC)
- C2 Corrigendum, OJ No L 157, 24. 6. 1988, p. 38 (88/233/EEC)
- C3 Corrigendum, OJ No L 199, 13. 7. 1989, p. 23 (89/174/EEC)
- C4 Corrigendum, OJ No L 273, 25. 10. 1994, p. 38 (94/32/EC)

COUNCIL DIRECTIVE
of 27 July 1976
on the approximation of the laws of the Member States relating to cosmetic products

(76/768/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas the provisions laid down by law, regulation or administrative action in force in the Member States define the composition characteristics to which cosmetic products must conform and prescribe rules for their labelling and for their packaging; whereas these provisions differ from one Member State to another;

Whereas the differences between these laws oblige Community cosmetic producers to vary their production according to the Member State for which the products are intended; whereas, consequently, they hinder trade in these products and, as a result, have a direct effect on the establishment and functioning of the common market;

Whereas the main objective of these laws is the safeguarding of public health and whereas, as a result, the pursuit of the same objective must inspire Community legislation in this sector; whereas, however, this objective must be attained by means which also take account of economic and technological requirements;

Whereas it is necessary to determine at Community level the regulations which must be observed as regards the composition, labelling and packaging of cosmetic products;

⁽¹⁾ OJ No C 40, 8. 4. 1974, p. 71.

⁽²⁾ OJ No C 60, 26. 7. 1973, p. 16.

Whereas this Directive relates only to cosmetic products and not to pharmaceutical specialities and medicinal products; whereas for this purpose it is necessary to define the scope of the Directive by delimiting the field of cosmetics from that of pharmaceuticals; whereas this delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use; whereas this Directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease; whereas, moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics;

Whereas in the present state of research, it is advisable to exclude cosmetic products containing one of the substances listed in Annex V from the scope of this Directive;

Whereas cosmetic products must not be harmful under normal or foreseeable conditions of use; whereas in particular it is necessary to take into account the possibility of danger to zones of the body that are contiguous to the area of application;

Whereas, in particular, the determination of the methods of analysis together with possible modifications or additions which may have to be made to them on the basis of the results of scientific and technical research, are implementing measures of a technical nature; whereas it is advisable to entrust their adoption to the Commission, subject to certain conditions specified in this Directive, for the purpose of simplifying and accelerating the procedure;

Whereas technical progress necessitates rapid adaptation of the technical provisions defined in this Directive and in subsequent Directives in this field; whereas it is advisable, in order to facilitate implementation of the measures necessary for this purpose, to provide for a procedure establishing close cooperation between the Member States and the Commission within the Committee for adaptation to technical progress of Directives aimed at the removal of technical obstacles to trade in the cosmetic products sector;

Whereas it is necessary, on the basis of scientific and technical research, to draw up proposals for lists of authorized substances which could include antioxidants, hair dyes, preservatives and ultraviolet filters, taking into account in particular the problem of sensitization;

Whereas it could happen that although conforming to the provisions of this Directive and its Annexes, cosmetic products placed on the market might endanger public health; whereas it is therefore advisable to provide for a procedure intended to remove this danger,

HAS ADOPTED THIS DIRECTIVE:

<i>Article 1</i>	76/768/EEC
1. A “cosmetic product” shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.	93/35/EEC
2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.	76/768/EEC
3. Cosmetic products containing one of the substances listed in Annex V shall be excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to those products.	88/667/EEC
<i>Article 2</i>	93/35/EEC
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, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.	
The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.	
<i>Article 3</i>	76/768/EEC
Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.	
<i>Article 4</i>	82/368/EEC
1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:	
(a) substances listed in Annex II;	
(b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;	

(c) colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair;	88/667/EEC
(d) colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;	
(e) preservatives other than those listed in Annex VI, Part 1;	82/368/EEC
(f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product;	
(g) UV filters other than those listed in Part 1 of Annex VII;	83/574/EEC
(h) UV filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein;	
(i) ingredients or combinations of ingredients tested on animals after <u>30 June 2000</u> in order to meet the requirements of this Directive.	93/35/EEC 97/18/EC
<p>If there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a sufficient period, and in any case for no less than two years, in accordance with the procedure laid down in Article 10. Before submitting such measures, the Commission will consult the Scientific Committee on Cosmetology.</p>	

The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals. That report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Commission shall in particular ensure the development, validation and legal acceptance of experimental methods which do not use live animals.

93/35/EEC

2. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2.

82/368/EEC

Article 5

88/667/EEC

Member States shall allow the marketing of cosmetic products containing:

- (a) the substances listed in Annex III, Part 2, within the limits and under the conditions laid down, up to the dates in column (g) of that Annex;
- (b) the colouring agents listed in Annex IV, Part 2, within the limits and under the conditions laid down, until the admission dates given in that Annex;
- (c) the preservatives listed in Annex VI, Part 2, within the limits and under the condition laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product;
- (d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

At these dates, these substances, colouring agents, preservatives and UV filters shall be:

- definitively allowed, or
- definitively prohibited (Annex II), or
- maintained for a given period specified in Part 2 of Annexes III, IV, VI and VII, or

- deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.

88/667/EEC

Article 5a

93/35/EEC

1. No later than 14 December 1994 the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.

For the purposes of this Article, “cosmetic ingredient” shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.

2. The inventory shall contain information on:

- the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organization, the EINECS, IUPAC, CAS and colour index numbers, and the common name referred to in Article 7 (2),
- the usual function(s) of the ingredient in the final product,
- where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.

3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.

Article 6

88/667/EEC

1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone:

93/35/EEC

- (a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community;

- b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;
- c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2.

88/667/EEC

The date of minimum durability shall be indicated by the words: "Best used before the end of..." followed by either:

- the date itself, or
- details of where the date appears on the packaging.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

The date shall be clearly expressed and shall consist of the month and the year in that order. Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months;

- (d) particular precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label" in Annexes III, IV, VI and VII, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging;

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(e) the batch number of manufacture or the reference for identifying the goods. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging; 88/667/EEC

(f) the function of the product, unless it is clear from the presentation of the product; 93/35/EEC

(g) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word “ingredients”. Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging.

The following shall not, however, be regarded as ingredients:

- impurities in the raw materials used,
- subsidiary technical materials used in the preparation but not present in the final product,
- materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

Perfume and aromatic compositions and their raw materials shall be referred to by the word “perfume” or “flavour”. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms “may contain” are added.

An ingredient must be identified by the common name referred to in Article 7 (2) or, failing that, by one of the names referred to in Article 5a (2), first indent.

In accordance with the procedure laid down in Article 10, the Commission shall, no later than 14 December 1994, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.

Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached to the cosmetic product.

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In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

2. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

88/667/EEC

3. Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have. Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.

93/35/EEC

Article 7

76/768/EEC

1. Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.

2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.

93/35/EEC

3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.

Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

93/35/EEC

Article 7a

1. The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):

- (a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;
- (b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- (c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;
- (d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

- (e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;
- (f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

93/35/EEC

2. The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances ⁽³⁾.

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

The Member States shall ensure that the abovementioned authorities continue to cooperate in areas where such cooperation is necessary to the smooth application of this Directive.

Article 8

82/368/EEC

1. In accordance with the procedure laid down in Article 10 the following shall be determined:

- the methods of analysis necessary for checking the composition of cosmetic products,
- the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.

2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the Scientific Committee on Cosmetology, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.

93/35/EEC

⁽³⁾ OJ No L 15, 17. 1. 1987, p. 29.

Article 8a

82/368/EEC

1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

- (a) the authorization must be limited to a maximum period of three years;
- (b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;
- (c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member States shall forward to the Commission and to the other Member States the text of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Scientific Committee for Cosmetology and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Article 9

76/768/EEC

1. The Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector, hereinafter called 'the Committee', is hereby set up. It shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 10

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.
2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman according to the urgency of the matter. Opinions shall be adopted by a majority of 54 votes, the votes of Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.
3. (a) The Commission shall adopt the proposed measures when they are in accordance with the opinion of the Committee.
 - (b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.
 - (c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

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Act of Accession ES, PT

Article 11

Without prejudice to Article 5 and not later than one year after expiry of the period laid down in Article 14 (1) for implementation of this Directive by the Member States, the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances.

Article 12

1. If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.
2. The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.

88/667/EEC

3. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

76/768/EEC

Article 13

Precise reasons shall be stated for any individual measures placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Directive. It shall be notified to the party concerned together with particulars of the remedies available to him under the laws in force in the Member States and of the time limits allowed for the exercise of such remedies.

Article 14

1. Member States shall bring into force the provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.
2. Member States may, however, for a period of 36 months from notification of this Directive, authorize the marketing in their territory of cosmetic products which do not conform to the requirements of the Directive.
3. Member States shall ensure that the texts of such provisions of national law as they adopt in the field governed by this Directive are communicated to the Commission.

Article 15

This Directive is addressed to the Member States.

ANNEX I

76/768/EEC

ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc.).
- Depilatories.
- Deodorants and anti-perspirants.
- Hair care products:
 - hair tints and bleaches,
 - products for waving, straightening and fixing,
 - setting products,
 - cleansing products (lotions, powders, shampoos),
 - conditioning products (lotions, creams, oils),
 - hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc.).
- Products for making up and removing makeup from the face and the eyes.
- Products intended for application to the lips.
- Products for care of the teeth and the mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.
- Anti-wrinkle products.

<i>ANNEX II</i>	76/768/EEC
LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS	82/368/EEC
1. N-5-Chlorobenzoxazol-2-ylacetamide	76/768/EEC
2. <u>2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts</u>	82/368/EEC
3. Deanol aceglumate* ⁽¹⁾	
4. Spironolactone*	
5. <u>[4-(4-Hydroxy-3-iodophenoxy)-3,5-diodophenyl]acetic acid and its salts</u>	82/368/EEC
6. Methotrexate*	
7. Aminocaproic acid* and its salts	
8. Cinchophen*, its salts, derivatives and salts of these derivatives	
9. Thyropropic acid* and its salts	
10. Trichloroacetic acid	
11. <i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)	
12. Aconitine (principal alkaloid of <i>Aconitum napellus</i> L.) and its salts	
13. <i>Adonis vernalis</i> L. and its preparations	
14. Epinephrine*	
15. <i>Rauwolfia serpentina</i> alkaloids and their salts	
16. Alkyne alcohols, their esters, ethers and salts	
17. Isoprenaline*	
18. Allyl isothiocyanate	
19. Alloclamide* and its salts	
20. Nalorphine*, its salts and ethers	
21. Sympathicomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe	
22. Aniline, its salts and its halogenated and sulphonated derivatives	
23. Betoxycaïne* and its salts	
24. Zoxazolamine*	
25. Procainamide*, its salts and derivatives	
26. Benzidine	
27. Tuaminoheptane*, its isomers and salts	
28. Octodrine* and its salts	
29. <u>2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts</u>	82/368/EEC
30. 1,3-dimethylpentylamine and its salts	
31. 4-Aminosalicylic acid and its salts	

⁽¹⁾ In this Directive, names followed by an asterisk are those published in 'Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1–33 of proposed INN', WHO, Geneva, August 1975.

32. Toluidines, their isomers, salts and halogenated and sulpho-nated derivatives	76/768/EEC
33. Xylidines, their isomers, salts and halogenated and sulpho-nated derivatives	
34. <u>Imperatorin (9-(3-methoxybut-2-enyloxy)furo[3,2-g]chromen-7-one)</u>	82/368/EEC
35. <i>Ammi majus</i> and its galenical preparations	
36. 2,3-Dichloro-2-methylbutane	
37. Substances with androgenic effect	
38. Anthracene oil	
39. Antibiotics ———	90/121/EEC – deleted
40. Antimony and its compounds	
41. <i>Apocynum cannabinum L.</i> and its preparations	
42. <u>Apomorphine (R 5,6,6a 7-tetrahydro-6-methyl-4H-dibenzo [de.g]quinoline-10,11-diol) and its salts</u>	82/368/EEC
43. Arsenic and its compounds	
44. <i>Atropa belladonna L.</i> and its preparations	
45. Atropine, its salts and derivatives	
46. Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, and lakes, salts and pigments prepared from the colouring agents listed with the reference (5) in Annex III, Part 2 and Annex IV, Part 2.	83/191/EEC
47. Benzene	76/768/EEC
48. <u>Benzimidazol-2(3H)-one</u>	82/368/EEC
49. <u>Benzazepines and benzodiazepines</u>	82/368/EEC
50. <u>1-Dimethylaminomethyl-1-methylpropyl benzoate (amyl-caine) and its salts</u>	82/368/EEC
51. <u>2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts</u>	82/368/EEC
52. <u>Isocarboxazid*</u>	82/368/EEC
53. Bendroflumethiazide* and its derivatives	
54. Beryllium and its compounds	
55. Bromine, elemental	
56. Bretylium tosilate*	
57. Carbromal*	
58. Bromisoval*	
59. Brompheniramine* and its salts	
60. Benzilonium bromide*	
61. Tetrylammonium bromide*	
62. Brucine	
63. Tetracaine* and its salts	
64. Mofebutazone*	
65. Tolbutamide*	
66. Carbutamide*	
67. Phenylbutazone*	
68. Cadmium and its compounds	

69. Cantharides, <i>Cantharis vesicatoria</i>	76/768/EEC
70. (1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)	
71. Phenprobamate*	
72. <u>Nitroderivatives of carbazole</u>	82/368/EEC
73. Carbon disulphide	
74. Catalase	
75. Cephaeline and its salts	
76. <i>Chenopodium ambrosioides</i> (essential oil)	
77. 2,2,2-Trichloroethane-1,1-diol	
78. Chlorine	
79. Chlorpropamide*	
80. <u>Diphenoxylate* hydrochloride</u>	82/368/EEC
81. 4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)	
82. Chlorzoxazone*	
83. 2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)	
84. Chlorprothixene* and its salts	
85. Clofenamide*	
86. <u>N,N-bis(2-chloroethyl)methylamine N-oxide and its salts</u>	82/368/EEC
87. Chlormethine* and its salts	
88. Cyclophosphamide* and its salts	
89. Mannomustine* and its salts	
90. Butanilicaine* and its salts	
91. <u>Chlormezanone*</u>	82/368/EEC
92. Triparanol*	
93. 2-[2-(4-Chlorophenyl)-2-phenylacetyl] indane-1,3-dione (chlorophacinone-ISO)	
94. Chlorphenoxamine*	
95. <u>2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan 1,3-dione (chlorophacinone — ISO)</u>	82/368/EEC
96. Chloroethane	
97. Chromium; chromic acid and its salts	
98. <i>Claviceps purpurea</i> Tul., its alkaloids and galenical preparations	
99. <i>Conium maculatum</i> L. (fruit, powder, galenical preparations)	
100. Glycyclamide*	
101. Cobalt benzenesulphonate	
102. Colchicine, its salts and derivatives	
103. Colchicoside and its derivatives	
104. <i>Golchicum autumnale</i> L. and its galenical preparations	
105. Convallatoxin	
106. <i>Anamirta cocculus</i> L. (fruit)	
107. <i>Croton tiglium</i> (oil)	
108. 1-Butyl-3-(N-crotonylsulphanilyl)urea	

109. Curare and curarine	76/768/EEC
110. Synthetic curarizants	
111. Hydrogen cyanide and its salts	
112. <u>2-α-Cyclohexylbenzyl(N,N,N',N',-tetraethyl)trimethylenediamine (phenetamine)</u>	82/368/EEC
113. Cyclomenol* and its salts	
114. Sodium hexacyclonate*	
115. Hexapropymate*	
116. Dextropropoxyphene*	
117. <u>O,O'-Diacetyl-N-allyl-N-normorphine</u>	82/368/EEC
118. Pipazetate* and its salts	
119. <u>5-($\alpha\beta$-Dibromophenethyl)-5-methylhydantoin</u>	82/368/EEC
120. <u>N,N'-Pentamethylenebis (trimethylammonium salts), e.g. pentamethonium bromide*</u>	82/368/EEC
121. <u>N,N'-[(Methylimino)diethylene]bis(ethyl dimethylammonium salts, e.g. azamethonium bromide*)</u>	82/368/EEC
122. Cyclarbamate*	
123. Clofenotane* DDT (ISO)	
124. <u>N,N'-Hexamethylenebis(trimethylammonium) salts, e.g. hexamethonium bromide*</u>	82/368/EEC
125. Dichloroethanes (ethylene chlorides)	
126. Dichloroethylenes (acetylene chlorides)	
127. Lysergide* and its salts	
128. <u>2-Diethylaminoethyl-3-hydroxy-4-phenylbenzoate and its salts</u>	82/368/EEC
129. Cinchocaine* and its salts	
130. 3-Diethylaminopropyl cinnamate	
131. <u>O,O'-Diethyl O-4-nitrophenyl phosphorothioate (parathion—ISO)</u>	82/368/EEC
132. <u>[Oxalylbisiminoethylene]bis(o-chlorobenzyl)diethylammonium salts, e.g. ambenomium chloride*</u>	82/368/EEC
133. Methypylon* and its salts	
134. Digitaline and all heterosides of <i>Digitalis purpurea L.</i>	
135. 7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl]theophylline (xanthinol)	
136. Dioxethedrin* and its salts	
137. Piprocurarium*	
138. Propyphenazone*	
139. Tetrabenazine* and its salts	
140. Captodiame*	
141. Mefeclozazine* and its salts	
142. Dimethylamine	
143. <u>1,1-Bis(dimethylaminomethyl)propyl benzoate (amydricine, alpine) and its salts</u>	82/368/EEC
144. Methapyrilene* and its salts	
145. Metamfepramone* and its salts	
146. Amitriptyline* and its salts	
147. Metformin* and its salts	

148. Isosorbide dinitrate*	76/768/EEC
149. Malononitrile	
150. Succinonitrile	
151. Dinitrophenol isomers	
152. Inproquone*	
153. Dimevamide* and its salts	
154. Diphenylpyraline* and its salts	
155. Sulfinpyrazone*	
156. <u>N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e.g. isopropamide iodide*</u>	82/368/EEC
157. Benactyzine*	
158. Benzatropine* and its salts	
159. Cyclizine* and its salts	
160. <u>5,5-Diphenyl-4-imidazolidone</u>	82/368/EEC
161. Probenecid*	
162. Disulfiram* thiram (ISO)	
163. Emetine, its salts and derivatives	
164. Ephedrine and its salts	
165. Oxanamide* and its derivatives	
166. Eserine or physostigmine and its salts	
167. Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in <u>Annex VII, Part 2</u>	85/391/EEC
168. Choline salts and their esters, e.g. choline chloride	
169. Caramiphen* and its salts	
170. Diethyl 4-nitrophenyl phosphate	
171. Metethoheptazine* and its salts	
172. Oxpheneridine* and its salts	
173. Ethoheptazine* and its salts	
174. Methheptazine* and its salts	
175. Methylphenidate* and its salts	
176. Doxylamine* and its salts	
177. Tolboxane*	
178. 4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol	85/391/EEC
179. Parethoxycaine* and its salts	76/768/EEC
180. Fenozolone*	
181. Glutethimide* and its salts	
182. Ethylene oxide	
183. Bemegride* and its salts	
184. Valnoctamide*	
185. Haloperidol*	
186. Paramethasone*	
187. Fluanisone*	
188. Trifluoperidol*	

189. Fluoresone*	76/768/EEC
190. Fluorouracil*	
191. Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1	82/368/EEC
192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*	76/768/EEC
193. Galantamine*	
194. Progestogens, ———	90/121/EEC – deleted
195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)	
196. <u>(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethano-naphthalene (endrin—ISO)</u>	82/368/EEC
197. Hexachloroethane	
198. <u>(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethano-naphthalene (isodrin-ISO)</u>	
199. Hydrastine, hydrastinine and their salts	
200. Hydrazides and their salts	
201. Hydrazine, its derivatives and their salts	
202. Octamoxin* and its salts	
203. Warfarin* and its salts	
204. <u>Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid</u>	82/368/EEC
205. Methocarbamol*	
206. Propatylnitrate*	
207. <u>4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin</u>	82/368/EEC
208. Fenadiazole*	
209. Nitroxoline* and its salts	
210. Hyoscyamine, its salts and derivatives	
211. <i>Hyoscyamus niger L.</i> (leaves, seeds, powder and galenical preparations)	
212. Pemoline* and its salts	
213. Iodine	
214. <u>Decamethylenebis(trimethylammonium) salts, e.g. decamethonium bromide</u>	82/368/EEC
215. Ipecacuanha (<i>Cephaelis ipecacuanha Brot.</i> and related species) (roots, powder and galenical preparations)	
216. (2-Isopropylpent-4-enoyl)urea (apronalide)	
217. <u>α-Santonin [(3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto [1,2-b] furan-2,8-dione]</u>	82/368/EEC
218. <i>Lobelia inflata L.</i> and its galenical preparations	
219. Lobeline* and its salts	
220. Barbiturates	
221. Mercury and its compounds, except those special cases included in Annex VI, Part 1	86/199/EEC 91/184/EEC
222. 3,4,5-Trimethoxyphenethylamine and its salts	76/768/EEC
223. Metaldehyde	
224. 2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts	

225. Coumetarol*	76/768/EEC
226. Dextromethorphan* and its salts	
227. 2-Methyiheptylamine and its salts	
228. Isometheptene* and its salts	
229. Mecamylamine*	
230. Guaifenesin*	
231. Dicoumarol*	
232. Phenmetrazine*, its derivatives and salts	
233. Thiamazole*	
234. <u>3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H-pyrano [3,2-c]-[1] benzopyran-5-one (cyclocoumarol)</u>	82/368/EEC
235. Carisoprodol*	
236. Meprobamate*	
237. Tefazoline* and its salts	
238. Arecoline	
239. Poldine metilsulfate*	
240. Hydroxyzine*	
241. 2-Naphthol	
242. 1-and 2-Naphthylamines and their salts	
243. <u>3-(1-Naphthyl)-4-hydroxycoumarin</u>	82/368/EEC
244. Naphazoline* and its salts	
245. Neostigmine and its salts (e.g. neostigmine bromide*)	
246. Nicotine and its salts	
247. Amyl nitrites	
248. Inorganic nitrites, with the exception of sodium nitrite	
249. Nitrobenzene	
250. Nitroresols and their alkali metal salts	
251. Nitrofurantoin*	
252. Furazolidone*	
253. Propane-1,2,3-triyl trinitrate	
254. Acenocoumarol*	
255. Alkali pentacyanonitrosylferrate (2-)	
256. Nitrostilbenes, their homologues and their derivatives	
257. Noradrenaline and its salts	
258. Noscapine* and its salts	
159. Guanethidine* and its salts	
260. Oestrogens, ———	89/174/EEC – deleted
261. Oleandrin	
262. Chlortalidone*	
263. Pelletierine and its salts	
264. Pentachloroethane	
265. Pentaerithrityl tetranitrate*	
266. Petrichloral*	
267. Octamylamine* and its salts	
268. Picric acid	82/368/EEC

269. Phenacemide*	76/768/EEC
270. Difendoxazine*	
271. <u>2-Phenylindan-1,3-dione (phenindione)</u>	82/368/EEC
272. Ethylphenacemide*	
273. Phenprocoumon*	
274. Fenyramidol*	
275. Triamterene* and its salts	
276. <u>Tetraethyl pyrophosphate: TEPP (ISO)</u>	82/368/EEC
277. Tritolyl phosphate	
278. Psilocybine*	
279. Phosphorus and metal phosphides	
280. Thalidomide* and its salts	
281. <i>Physostigma venenosum Balf.</i>	
282. Picrotoxin	
283. Pilocarpine and its salts	
284. <u>α-Piperidin-2-ylbenzyl acetate (SIC! acetate) laevorotatory threoform (levophaceterane) and its salts</u>	82/368/EEC
285. Pipradrol* and its salts	
286. Azacyclonol* and its salts	
287. Bietamiverine*	
288. Butopirine* and its salts	
289. Lead and its <u>compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated</u>	90/121/EEC
290. Conjine	
291. <i>Prunus laurocerasus L.</i> ('cherry laurel water')	
292. Metyrapone*	
293. Radioactive substances ⁽¹⁾	
294. <i>Juniperus sabina L.</i> (leaves, essential oil and galenical preparations)	
295. Hyoscine, its salts and derivatives	
296. Gold salts	
297. Selenium and its compounds with the exception of selenium disulphide under the conditions set out under reference No 49 in Annex III, Part 1	85/391/EEC
298. <i>Solanum nigrum L.</i> and its galenical preparations	76/768/EEC
299. Sparteine and its salts	
300. Glucocorticoids	
301. <i>Datura stramonium L.</i> and its galenical preparations	

⁽¹⁾ The presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment is permitted, provided that the radioactive substances are not enriched for the manufacture of cosmetic products and that their concentration falls within the limits set in the Directive laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations (OJ No 11, 20. 2. 1959, p. 221/59).

302. Strophantines, their aglucones and their respective derivatives	76/768/EEC
303. <i>Strophantus</i> species and their galenical preparations	
304. Strychnine and its salts	
305. <i>Strychnos</i> species and their galenical preparations	
306. Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961	
307. <u>Sulphonamides (sulphanilamide and its derivatives...) and their salts obtained by substitution of one or more H-atoms of the -NH₂ groups) and their salts</u>	82/368/EEC
308. Sultiame*	
309. Neodymium and its salts	
310. Thiotepa*	
311. <i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	
312. Tellurium and its compounds	
313. <u>Xylometazoline* and its salts</u>	82/368/EEC
314. Tetrachloroethylene	
315. Carbon tetrachloride	
316. Hexaethyl tetraphosphate	
317. Thallium and its compounds	
318. <i>Thevetia nerifolia</i> Juss., glycoside extract	
319. Ethionamide*	
320. Phenothiazine* and its compounds	
321. Thiourea and its derivatives, with the exception of the one listed in Annex III, Part 1	82/368/EEC
322. Mephenesin* and its esters	76/768/EEC
323. Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147, 9. 6. 1975, p. 13)	
324. Tranlycypromine* and its salts	
325. Trichloronitromethane (chloropicrine)	
326. 2,2,2-Tribromoethanol (tribromoethyl alcohol)	
327. Trichiormethine* and its salts	
328. Tretamine*	
329. Gallamine triethiodide*	
330. <i>Urginea scilla</i> Stern. and its galenical preparations	
331. Veratrine, its salts and galenical preparations	
332. <i>Schoenocaulon officinale</i> Lind. (seeds and galenical preparations)	
333. <i>Veratrum</i> Spp. and their preparations	84/415/EEC
334. Vinyl chloride monomer	76/768/EEC
335. Ergocalciferol* and cholecalciferol (vitamins D ₂ and D ₃)	

336. Salts of <i>O</i> -alkyldithiocarbonic acids	76/768/EEC
337. Yobimbine and its salts	
338. Dimethyl sulfoxide*	
339. Diphenhydramine* and its salts	
340. 4-tert-Butylphenol	
341. 4-tert-Butylpyrocatechol	
342. Dihydrotachysterol	
343. Dioxane	
344. Morpholine and its salts	
345. <i>Pyrethrum album L.</i> and its galenical preparations	
346. <u>2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyl dimethylamine maleate</u>	82/368/EEC
347. Tripelennamine*	
348. Tetrachlorosalicylanilides	
349. Dichlorosalicylanilides	
350. Tetrabromosalicylanilides ———	83/368/EEC – 88/233/EEC – deleted
351. Dibromosalicylanilides, ———	88/233/EEC – deleted
352. Bithionol*	76/768/EEC
353. Thiuram monosulphides	
354. Thiuram disulphides	
355. Dimethylformamide	
356. 4-Phenylbut-3-en-2-one	
357. Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used	
358. Furocoumarines (e.g. trioxysalan*, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg.	95/34/EC
359. Oil from the seeds of <i>Laurus nobilis L.</i>	76/768/EEC
360. Safrole except for normal content in the natural essences used and provided the concentration does not exceed: 100 ppm in the finished product, 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children	82/368/EEC
361. 5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodite	76/768/EEC
362. 3'-ethyl-5',6',7,8'-tetrahydro-5',6',8,8'-tetramethyl-2'-acetonaphthone; Syn.: 1,1,4,4-tetramethyl-6-ethyl-7-acetyl-1,2,3,4-tetrahydronaphthalene (acetyl ethyl tetramethyl tetralin, AETT)	82/147/EEC

363. <i>O</i> -phenylenediamine and its salts	83/341/EEC
364. 4-methyl- <i>m</i> -phenylenediamine and its salts.	
365. Aristolochic acid and its salts	84/415/EEC
366. Chloroform	86/179/EEC
367. 2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin ———	88/233/EEC – deleted
368. 2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	
369. Pyrithione sodium (INN)	
370. <i>N</i> -(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)	87/137/EEC
371. 2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)	
372. 6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (Minoxidil) and its salts and derivatives	
373. <u>3,4',5-Tribromosalicylanide (Tribromsalan)</u>	88/233/EEC – C2, OJ No L 157, 24. 6. 1988, p. 38
374. <i>Phytolacca</i> spp. and their preparations	
375. Tretinoin (retinoic acid and its salts)	
376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole — CI 76050) <u>and their salts</u>	90/121/EEC
377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) <u>and their salts</u>	90/121/EEC
378. Colouring agent CI 12140	
379. Colouring agent CI 26105	
380. Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2	
381. Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))	89/174/EEC
382. Benzoyl peroxide	
383. 2-Amino,4-nitrophenol	
384. 2-Amino-5-nitrophenol	
385.11 α -Hydroxypregn-4-ene-3,20-dione and its esters	90/121/EEC
386. Colouring agent CI 42 640	
387. Colouring agent CI 13 065	
388. Colouring agent CI 42 535	
389. Colouring agent CI 61 554	
390. Antiandrogens with steroid structure	
391. Zirconium and its compounds, with the exception of the complexes under reference number 50 in Annex III (Part 1) and of zirconium lakes, salts and pigments of colouring agents listed with reference number 3 in Annex IV (Part 1)	
392. Thyrothricine	
393. Acetonitrile	
394. Tetrahydrozoline and its salts	

395. Hydroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in Annex III, Part 1	91/184/EEC
396. Dithio-2,2-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) – (pyrithione disulphide + magnesium sulphate)	
397. Colouring agent CI 12075 and its lakes, pigments and salts	
398. Colouring agent CI 45170 and CI 45170:1	
399. Lidocaine	
400. 1,2-epoxybutane	92/86/EEC
401. Colouring agent CI 15585	
402. Strontium lactate	
403. Strontium nitrate	
404. Strontium polycarboxylate	
405. Pramocaine	
406. 4-ethoxy-m-phenylenediamine and its salts	
407. 2,4-diaminophenylethanol and its salts	
408. Catechol	
409. Pyrogallol	
410. Nitrosamines	
411. Secondary dialkanolamines	
412. 4-Amino-2-nitrophenol	93/47/EEC
413. 2-Methyl-m-phenylenediamine	94/32/EC
414. 4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)	95/34/EC
—————	97/45/EC – deleted
416. Cells, tissues or products of human origin	95/34/EC
417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein*)	
418. 3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)	96/41/EC
419. (a) the skull, including the brain and eyes, tonsils and spinal cord of: <ul style="list-style-type: none"> — bovine animals aged 12 months, — ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum; (b) the spleens of ovine and caprine animals and ingredients derived therefrom. <p>However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:</p> <ul style="list-style-type: none"> — Transesterification or Hydrolysis at at least: 200 °C, 40 bars (40 000 hPa) for 20 minutes (glycerol and fatty acids and esters), 	98/16/EC

— Saponification with NaOH 12M (glycerol and soap):	98/16/EC
— Batch process: at 95 °C for three hours	
or	
— Continuous process: at 140 °C, two bars (2 000 hPa) for eight minutes or equivalent conditions.	
420. Crude and refined coal tars	97/45/EC
421. 1,1,3,3,5,-Pentamethyl-4,6-dinitroindane (moskene)	98/62/EC
422. 5- <i>tert</i> -Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene).	

76/768/EEC

82/368/EEC

ANNEX III

PART 1

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1	Boric acid	(a) Talcs (b) Products for oral hygiene (c) Other products	(a) 5 % (b) 0,5 % (c) 3 %	(a) Not to be used in products for children under three years old	(a) Not to be used for children under three years of age
2a	Thioglycollic acid and its salts	(a) Hair waving or straightening products: — general use — professional use (b) Depilatories (c) Other hair-care products which are removed after application	— 8 % ready for use pH 7 to 9,5 — 11 % ready for use pH 7 to 9,5 — 5 % ready for use pH 7 to 12,7 — 2 % ready for use pH 6 to 9,5 The abovementioned percentages are calculated as thioglycollic acid	(a) (b) (c): The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves ((a) and (c) only)	(a): — Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only (b) and (c): — Contains thioglycolate — Follow the instructions — Keep out of reach of children

88/233/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
2b	Thioglycollic acid esters	Hair waving or straightening products: — general use — professional use	— 8 % ready for use pH 6 to 9,5 — 11 % ready for use pH 6 to 9,5 The abovementioned percentages are calculated as thioglycollic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — May cause sensitization in the event of skin contact — avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves	— Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only
3	Oxalic acid, its esters and alkaline salts	Hair care products	5 %		For professional use only
4	Ammonia		6 % calculated as NH ₃		Above 2 %: contains ammonia
5	Tosylchloramide sodium (*)		0-2 %		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5 % (b) 3 %		

88/233/EEC

C2, OJ No L 157, 24. 6. 1988, p. 38.

82/368/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
7	Dichloromethane		35 % (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 %)	0.2 % as maximum impurity content	
8	<u>m- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-phenylenediamines (1)</u>	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	6 % calculated as free base		(a) Can cause an allergic reaction. — Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. — <u>Wear suitable gloves.</u>
9	<u>Methylphenylenediamines, their N-substituted derivatives and their salts (1) with the exception of substance No. 364 in Annex II</u>	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. — Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. — <u>Wear suitable gloves.</u>

83/341/EEC

92/86/EEC – deleted

92/86/EEC – deleted
93/47/EEC

83/341/EEC

92/86/EEC – deleted.

92/86/EEC – deleted
93/47/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
10	Diaminophenols (1)	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. — Contains diaminophenols. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains diaminophenols. Can cause allergic reaction. — <u>Wear suitable gloves.</u>
11	Dichlorophen (*)		0,5 %		
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	12 % of H ₂ O ₂ (40 volumes), present or released 4 % of H ₂ O ₂ present or released 2 % of H ₂ O ₂ present or released 0,1 % of H ₂ O ₂ present or released		(a): <u>Wear suitable gloves</u> (b) (c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them

92/86/EEC -- deleted

92/86/EEC -- deleted
93/47/EEC

87/137/EEC

92/86/EEC -- 93/47/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde (3).
14	Hydroquinone (2)	(a) Oxidizing colouring agent for hair-dyeing: 1. General use 2. Professional use (b) Agents for localized skin lightener	2 % 2 %		(a) 1. Do not use to dye eye-dashes or eyebrows Rinse the eyes immediately if the product comes into contact with them. Contains hydroquinone 2. For professional use only Contains hydroquinone Rinse the eyes immediately if the product comes into contact with them (b) — Contains hydroquinone — Avoid contact with the eyes — Apply to small areas — If irritation develops discontinue use

84/415/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent (b) Hair straightener 1. General use 2. Professional use (c) pH adjuster — depilatories (d) Other uses as pH adjuster	(a) 5 % by weight ⁽⁴⁾ (b) 1. 2 % by weight ⁽⁴⁾ 2. 4,5 % by weight ⁽⁴⁾ (c) Up to pH 12,7 (d) Up to pH 11		— Do not use on children under the age of 12 (a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children (b) 1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children 2. For professional use only. Avoid contact with eyes. Can cause blindness. (c) Keep out of reach of children. Avoid contact with eyes

96/41/EC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15b	Lithium hydroxide	(a) Hair straightener 1. General use 2. Professional use (b) Other uses	1. 2 % by weight ⁽⁴⁾ 2. 4,5 % by weight ⁽⁴⁾		1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children 2. For professional use only. Avoid contact with eyes. Can cause blindness
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) Other uses	7 % by weight calcium hydroxide		Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children.
16	α -naphthol	Colouring agent for hair dyeing	0,5 %		Contains α -naphthol
17	Sodium nitrite	Rust inhibitor	0,2 %	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0,3 %		
19	Phenol and its alkali salts	Soaps and shampoos	1 % calculated as phenol		Contains phenol
—					

92/86/EEC -- deleted

82/368/EEC

96/41/EC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0,5 % calculated as quinine base (b) 0,2 % calculated as quinine base		
22	Resorcinol (2)	(a) Oxidizing colouring agent for hair dyeing 1. general use 2. professional use (b) Hair lotions and shampoos	(a) 5 % (b) 0,5 %		(a) 1. Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them 2. For professional use only. Contains resorcinol. Rinse eyes immediately if product comes into contact with them (b) Contains resorcinol
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2 % calculated as sulphur pH \leq 12,7 (b) 6 % calculated as sulphur pH \leq 12,7		(a) Keep out of reach of children. Avoid contact with eyes (b) Keep out of reach of children. Avoid contact with eyes

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrrithione		1 % calculated as zinc		
25	Zinc 4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6 % calculated as % of anhydrous substance		Avoid contact with eyes
26	Sodium monofluorophosphate	Oral hygiene products	0,15 % calculated as F; When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains ammonium monofluorophosphate
27	Sodium monofluorophosphate	Ditto	0,15 % Ditto		Contains sodium monofluorophosphate
28	Potassium monofluorophosphate	Ditto	0,15 % Ditto		Contains potassium monofluorophosphate
29	Calcium monofluorophosphate	Ditto	0,15 % Ditto		Contains calcium monofluorophosphate
30	Calcium fluoride	Ditto	0,15 % Ditto		Contains calcium fluoride
31	Sodium fluoride	Ditto	0,15 % Ditto		Contains sodium fluoride
32	Potassium fluoride	Ditto	0,15 % Ditto		Contains potassium fluoride
33	Ammonium fluoride	Ditto	0,15 % Ditto		Contains ammonium fluoride
34	Aluminium fluoride	Ditto	0,15 % Ditto		Contains aluminium fluoride
35	Stannous fluoride	Ditto	0,15 % Ditto		Contains stannous fluoride

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
36	Hexadecyl ammonium fluoride	Ditto	0,15 % Ditto		Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride	Ditto	0,15 % Ditto		Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride
38	N,N',N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride	Ditto	0,15 % Ditto		Contains N,N',N'-tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride
39	Octadecenyl-ammonium fluoride	Ditto	0,15 % Ditto		Contains octadecenyl-ammonium fluoride
40	Sodium fluorosilicate	Ditto	0,15 % Ditto		Contains sodium fluorosilicate
41	Potassium fluorosilicate	Ditto	0,15 % Ditto		Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Ditto	0,15 % Ditto		Contains ammonium fluorosilicate
43	Magnesium fluorosilicate	Ditto	0,15 % Ditto		Contains (SIC) Contains magnesium fluorosilicate
44	1,3-Bis (hydroxymethyl)-imidazolidine-2-thione	(a) Hair-care preparations (b) Nail-care preparations	(a) Up to 2 % (b) Up to 2 %	(a) Prohibited in aerosol dispensers (sprays) (b) The pH of the product as applied must be less than 4	Contains 1,3-bis (hydroxymethyl) imidazolidine-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavourings			

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
46	6-methylcoumarin	Oral hygiene products	0,003 %		
47	Nicomethanol hydrofluoride	Oral hygiene products	0,15 % calculated as F When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains nicomethanol hydrofluoride
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4 %		— Contains silver nitrate — Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Antidandruff shampoos	1 %		— Contains selenium disulphide — Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxyde complexes AlKZr(OH)yClz and the aluminium zirconium chloride hydroxyde glycine complexes	Antiperspirants	20 % as anhydrous aluminium zirconium chloride hydroxyde 5,4 % as zirconium 5,4 % as zirconium	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between two and 10 2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0,9 and 2,1 3. Prohibited in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin

83/191/EEC

84/415/EEC

85/391/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
51	Quinolin-8-ol and bis (8-hydroxy-quinolinium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations	0,3 % calculated as base 0,03 % calculated as base		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % ethanol and isopropyl alcohol		
53	Etidronic acid (1-hydroxyethylene-di-phosphonic acid and its salts)	(a) Hair-care (b) Soap	1,5 % expressed as etidronic acid 0,2 % expressed as etidronic acid		—
54	1-Phenoxy-propan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2,0 %	As a preservative, see Annex VI, Part 1, No 43	

87/137/EEC

88/233/EEC – 89/174/EEC – deleted

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
55	Lead acetate	Only for hair-dyeing	0,6 % calculated in lead		Keep away from children. Avoid all contact with the eyes. Wash hands after use. Contains lead acetate. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops, discontinue use.
56	Magnesium fluoride	Dental hygiene products	0,15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains magnesium fluoride
57	Strontium chloride hexahydrate	(a) Toothpaste (b) Shampoo and face care products	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 % 2,1 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 2,1 %		Contains strontium chloride. Frequent use by children is not advisable

90/121/EEC

91/184/EEC

98/62/EC

82/368/EEC

Reference number	Substance	Restrictions				Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	
58	Strontium acetate hemihydrate	Toothpaste	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 %		Contains strontium acetate. Frequent use by children is not advisable	
59	Talc; Hydrated magnesium silicate	(a) Powdery products intended to be used for children under three years of age (b) other products			a) <u>Keep powder away from children's nose and mouth</u>	
60	Fatty acid dialkanolamides		Maximum dialkanolamine content: 0,5 %	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Maximum dialkanolamine content: 5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers 		

92/86/EEC

94/32/EC
C4, OJ No L 273, 25. 10. 1994, p. 38.

92/86/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
61	Monoalkanolamines		Maximum dialkanolamine content: 0,5 %	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — Maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrite-free containers 	
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2,5 %	(a) (b): <ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrate-free containers 	

92/86/EEC

82/368/EEC

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
63	Strontium hydroxide	pH-regulator in depilatory products	3,5 % calculated as strontium, max. pH of 12,7		<ul style="list-style-type: none"> — Keep out of reach of children — Avoid contact with the eyes
64	Strontium peroxide	Rinse-off hair care preparations professional use	4,5 % calculated as strontium in the ready-for-use preparation	All products must meet the hydrogen peroxide release requirements	<ul style="list-style-type: none"> — Avoid contact with eyes — Rinse eyes immediately if product comes into contact with them — For professional use only — Wear suitable gloves

94/32/EC

(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 authorized for each of them does not exceed 1.

(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 2.

(3) Only if the concentration exceeds 0,05 %.

(4) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column d.

82/368/EEC

96/41/EC

86/199/EEC – 88/667/EEC

Part 2

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
—						

95/34/EC – deleted

ANNEX IV

76/768/EEC

PART 1

86/179/EEC – 88/667/EEC

LIST OF COLOURING AGENTS ALLOWED FOR USE IN
COSMETIC PRODUCTS ⁽¹⁾

Field of application

Column 1 = Colouring agents allowed in all cosmetic products.

Column 2 = Colouring agents allowed in all cosmetic products
except those intended to be applied in the vicinity
of the eyes, in particular eye make-up and eye-
make-up remover.Column 3 = Colouring agents allowed exclusively in cosmetic
products intended not to come into contact with
the mucous membranes.Column 4 = Colouring agents allowed exclusively in cosmetic
products intended to come into contact only briefly
with the skin.

Colour index number or de- nomination	Colour	Field of application				Other limitations and requirements ⁽²⁾
		1	2	3	4	
10006	Green				X	
10020	Green			X		
10316 ⁽³⁾	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
—						91/184/EEC – deleted
12085 ⁽³⁾	Red	X				3 % maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	— 89/174/EEC – deleted
13015	Yellow	X				E 105
—						88/233/EEC – deleted
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E 125
15510 ⁽³⁾	Orange		X			
15525	Red	X				

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	86/179/EEC
		1	2	3	4		
15580	Red	X					
—							91/184/EEC – deleted
15620	Red				X		
15630 ⁽³⁾	Red	X				3 % maximum concentration in the finished product	
15800	Red			X		—	89/174/EEC – deleted
15850 ⁽³⁾	Red	X					
15865	Red	X					
15880	Red	X					
15980	Orange	X				E 111	
15985 ⁽³⁾	Yellow	X				E 110	
16035	Red	X					
16185	Red	X				E 123	
16230	Orange			X			
16255 ⁽³⁾	Red	X				E 124	
16290	Red	X				E 126	
17200 ⁽³⁾	Red	X					90/121/EEC
18050	Red			X			
18130	Red				X		
18690	Yellow				X		
18736	Red				X		
18820	Yellow				X		
18965	Yellow	X					
19140 ⁽³⁾	Yellow	X				E 102	
20040	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm	
20170	Orange			X			
20470	Black				X	—	89/174/EEC – deleted
21100	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm	
21108	Yellow				X	ditto	
21230	Yellow			X			
24790	Red				X		
26100	Red			X		Purity criteria: aniline ≤ 0,2 % 2-naphtol ≤ 0,2 % 4-aminoazobenzene ≤ 0,1 % 1-(phenylazo)-2-naphtol ≤ 3 % 1-[2-(phenylazo)phenylazo]-2-naphtalenol ≤ 2 %	92/86/EEC

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	86/179/EEC
		1	2	3	4		
27290 ⁽³⁾	Red				X	E 152	
27755	Black	X				E 152	
28440	Black	X				E 151	
40215	Orange				X		
40800	Orange	X					
40820	Orange	X				E 160 e	
40825	Orange	X				E 160 f	
40850	Orange	X				E 161 z	
42045	Blue			X		—	90/121/EEC – 90/121/EEC – deleted
42051 ⁽³⁾	Blue	X				E 131	
42053	Green	X					
42080	Blue	X			X		
42090	Blue						
42100	Green				X		
42170	Green				X	—	89/174/EEC – deleted
42510	Violet			X			
42520	Violet				X	5 ppm maximum concentration in the finished product	
—							90/121/EEC – deleted
42735	Blue			X			
44045	Blue			X		—	90/121/EEC – 90/121/EEC – deleted
44090	Green	X				E 142	
45100	Red				X		
—							91/184/EEC – deleted
—							91/184/EEC – deleted
45190	Violet				X	—	89/174/EEC – deleted
45220	Red				X		
45350	Yellow	X				6 % maximum concentration in the finished product	
45370 ⁽³⁾	Orange	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid	
45380 ⁽³⁾	Red	X				ditto	
45396	Orange	X				when used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 %	
45405	Red		X			not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	86/179/EEC
		1	2	3	4		
45410 ⁽³⁾	Red	X				ditto	
45425	Red	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 3 % 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid	
45430 ⁽³⁾	Red	X				E 127 ditto	
47000	Yellow			X		—	89/174/EEC – deleted
47005	Yellow	X				E 104	
50325	Violet				X		
50420	Black			X			
51319	Violet				X		
58000	Red	X					
59040	Green			X			
60724	Violet				X		
60725	Violet	X					
60730	Violet			X			
61565	Green	X					
61570	Green	X					
61585	Blue				X		
62045	Blue				X		
69800	Blue	X				E 130	
69825	Blue	X					
71105	Orange			X			
73000	Blue	X					
73015	Blue	X				E 132	
73360	Red	X					
73385	Violet	X					
73900	Violet				X	—	92/86/EEC – deleted
73915	Red				X		
74100	Blue				X		
74160	Blue	X					
74180	Blue				X	—	92/86/EEC – deleted
74260	Green		X				
75100	Yellow	X					
75120	Orange	X				E 160 b	
75125	Yellow	X				E 160 d	
75130	Orange	X				E 160 a	
75135	Yellow	X				E 161 d	
75170	White	X					
75300	Yellow	X				E 100	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	86/179/EEC
		1	2	3	4		
75470	Red	X				E 120	
75810	Green	X				E 140 and E 141	
77000	White	X				E 173	
77002	White	X					
77004	White	X					
77007	Blue	X					
77015	Red	X					
77120	White	X					
77163	White	X					
77220	White	X				E 170	
77231	White	X					
77266	Black	X					
77267	Black	X					
77268:1	Black	X				E 153	
77288	Green	X				free from chromate ion	87/137/EEC
77289	Green	X				free from chromate ion	
77346	Green	X					86/179/EEC
77400	Brown	X					
77480	Brown	X				E 175	
77489	Orange	X				E 172	
77491	Red	X				E 172	
77492	Yellow	X				E 172	
77499	Black	X				E 172	
77510	Blue	X				free from cyanide ions	
77713	White	X					
77742	Violet	X					
77745	Red	X					
77820	White	X				E 174	
77891	White	X				E 171	
77947	White	X					
Lactoflavin	Yellow	X				E 101	
Caramel	Brown	X				E 150	
Capsanthin, capsorubin	Orange	X				E 160 g	
Beetroot red	Red	X				E 162	
Anthocyanins	Red	X				E 162	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	86/179/EEC
		1	2	3	4		
Aluminium, zinc, magnesium and calcium stearates	White	X					
Bromothymol blue	Blue				X		
Bromocresol green	Green				X		
Acid red 195	Red			X			88/233/EEC

- (¹) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.
- (²) Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter 'E' has been deleted therefrom.
- (³) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 8.

86/179/EEC

PART 2

LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS ⁽¹⁾**Field of application**

- Column 1 = Colouring agents allowed in all cosmetic products.
- Column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover
- Column 3 = Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes.
- Column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements	Authorization valid until
		1	2	3	4		
—							

86/179/EEC

92/86/EEC – deleted

⁽¹⁾ Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.

<i>ANNEX V</i> LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THE DIRECTIVE	76/768/EEC
—	90/121/EEC – deleted
—	87/137/EEC – deleted
—	90/121/EEC – deleted
—	83/341/EEC – deleted
5. Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex II, strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in Annex III, Part 1 and of strontium lakes, pigments and salts of the colouring agents listed with the reference ⁽³⁾ in Annex IV, Part 1.	94/32/EC
—	90/121/EEC – deleted
—	91/184/EEC – deleted
—	90/121/EEC – deleted
—	86/179/EEC – deleted
—	84/415/EEC – deleted

ANNEX VI

86/199/EEC

**LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS
MAY CONTAIN**

PREAMBLE

1. Preservatives are substances which may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.
2. The substances marked with the symbol (*) may also be added to cosmetic products in concentration other than those laid down in this Annex for other specific purposes apparent from the presentation of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.
3. Other substances used in the formulation of cosmetic products may also have anti-microbial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in this Annex.
4. For the purposes of this list:
 - “Salts” is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
 - “Esters” is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.
5. All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning “contains formaldehyde” where the concentration of formaldehyde in the finished product exceeds 0,05 %.

LIST OF PRESERVATIVES ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid, its salts and esters (*)	0,5 % (acid)		
2	Propionic acid and its salts (*)	2 % (acid)		
3	Salicylic acid and its salts (*)	0,5 % (acid)	Not to be used in preparations for children under three years of age, except for shampoos	Not to be used for children under three years of age ⁽¹⁾
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (*)	0,6 % (acid)		
5	Formaldehyde paraformaldehyde	0,2 % (except for products for oral hygiene) 0,1 % (products for oral hygiene) 0,2 % expressed as the phenol	Prohibited in aerosol dispensers (sprays)	
—				
7	Biphenyl-2-ol (o-phenylphenol) and its salts (*)	0,2 % expressed as the phenol		
8	Pyrithione zinc (INN) (*)	0,5 %	Authorized in products rinsed off Forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogen-sulphites (*)	0,2 % expressed as free SO ₂		
10	Sodium iodate	0,1 %	Rinse-off products only	
11	Chlorobutanol (INN)	0,5 %	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol

⁽¹⁾ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

86/199/EEC

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
12	4-Hydroxybenzoic acid and its salts and esters (*)	4 % (acid) for 1 ester, 0,8 % (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydracetic acid) and its salts	0,6 % (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt (+)	0,5 % (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0,1 %		
16	Thiomersal (INN)	0,007 % (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0,007 %	For eye make-up and eye make-up remover only	Contains thiomersal
17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (*)	0,2 % (acid)	See Annex VI, Part 2, No 8	
19	Hexetidine (INN) (*)	0,1 %	—	
20	5-Bromo-5-nitro-1,3-dioxane	0,1 %	Rinse-off products only Avoid formation of nitrosamines	
21	Bronopol (INN) (*)	0,1 %	—	
22	2,4-Dichlorobenzyl alcohol (*)	0,15 %	Avoid formation of nitrosamines	

88/233/EEC – deleted

89/174/EEC – deleted

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
23	Trilocarban (INN) (*)	0,2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm	
24	4-Chloro-m-cresol (*)	0,2 %	Prohibited in the products intended to come into contact with mucous membranes	
25	Tricolosan (INN) (*)	0,3 %		
26	4-Chloro-3,5-xyleneol (*)	0,5 %		
27	3,3'-Bis (1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1,4-methylenediurea ("Imidazolidinyl urea") (*)	0,6 %		
28	Poly (1-hexamethylenebiguanide hydrochloride) (*)	0,3 %		
29	2-Phenoxyethanol (*)	1,0 %		
30	Hexamethylenetetramine (*) (methenamine) (INN)	0,15 %		
31	Methenamine 3-chloroallylochloride (INNM)	0,2 %		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*)	0,5 %		
33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (*)	0,6 %		
34	Benzyl alcohol (*)	1,0 %		
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt (*)	1,0 % 0,5 %	Products rinsed off For other products	
36	1,2-Dibromo-2,4-dicyanobutane	0,1 %	<u>Not to be used in cosmetic sun-screen products at a concentration exceeding 0.025 %</u>	

86/199/EEC

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen) (*)	0,1 %		
38	4-Isopropyl-m-cresol	0,1 %		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one		
40	2-Benzyl-4-chlorophenol (clorophene)	0,2 %		
41	2-Chloroacetamide	0,3 %		Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3 % expressed as clorhexidine		
43	1-Phenoxypropan-2-ol	1,0 %	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (*)	0,1 %		
45	4,4-dimethyl-1,3-oxazolidine	0,1 %	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl)-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0,5 %		
47	1,6-Di (4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (+)	0,1 %		

92/86/EEC

86/199/EEC

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
48	Glutaraldehyde (Pentane-1,5-dial)	0,1 %	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0,05 %)
49	5-Ethyl-3,7-dioxo-1-azabicyclo [3,3,0] octane	0,3 %	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
50	3-(p-chlorophenoxy)-propane-1,2 diol (chlorphenesin)	0,3 %		
51	Sodium hydroxymethylamino acetate (Sodium Hydroxymethylglycinate)	0,5 %		
52	Silver chloride deposited on titanium dioxide	0,004 % calculated as AgCl	20 % AgCl (W/W) on TiO ₂ . Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips	
53	Benzethonium chloride	0,1 %	Rinse-off products only	
54	Benzalkonium chloride, bromide and saccharinate (+)	0,1% calculated as benzalkonium chloride	Not for oral hygiene and lip products	

94/32/EC

96/41/EC

97/45/EC

98/62/EC

86/199/EEC

PART 2

LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	g	d	e	f
—					
—					
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21	Benzylhemiformal	0,03 %	For rinse-off products only		30. 6. 1999
—					

89/174/EEC – deleted

96/41/EC – deleted

89/174/EEC – deleted

91/184/EEC – deleted

89/174/EEC – deleted

91/184/EEC – deleted

88/233/EEC – deleted

87/137/EEC – deleted

88/233/EEC – deleted

87/137/EEC – deleted

88/233/EEC – deleted

95/34/EC – deleted

98/62/EC – deleted

91/184/EEC – deleted

88/233/EEC – deleted

89/174/EEC – deleted

92/86/EEC – deleted

94/32/EC – 98/62/EC

88/233/EEC – deleted

86/199/EEC

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	g	d	e	f
—					
—					
29	3-Iodo-2-propynyl butylcarbamate (iodo-propynyl butylcarbamate)	0,05 %	Not for oral hygiene and lip products		30. 6. 1999
—					

89/174/EEC – deleted

94/32/EC – deleted

98/62/EC

96/41/EC – deleted

ANNEX VII

List of UV filters which cosmetic products may contain

For the purposes of this Directive, UV filters are substances which, contained in cosmetic sun-screen products, are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays.

These UV filters may be added to other cosmetic products within the limits and under the conditions laid down in this Annex.

Other UV filters used in cosmetic products solely for the purpose of protecting the product against UV rays are not included in this list.

PART 1

List of permitted UV filters which cosmetic products may contain

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	4-Aminobenzoic acid	5 %		
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene-methyl) anilinium methyl sulphate	6 %		
3	Homosalate (INN)	10 %		
4	Oxybenzone (INN)	10 %		Contains oxybenzone (1)
—				
6	2-phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (expressed as acid)		
7	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2,2,1]hept-1-yl-methanesulfonic acid and its salts	10 % (expressed as acid)		
8	1-(4-tert-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5 %		
9	alpha-(2-Oxoborn-3-ylidene)-toluene-4-sulphonic acid and its salts	6 % (expressed as acid)		
10	2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester (Octocrylene)	10 % (expressed as acid)		
11	Polymer of N-[(2 and 4)-(2-oxoborn-3-ylidene)methyl]benzyl]acrylamide	6 %		
12	Octyl methoxycinnamate	10 %		

83/574/EEC

93/47/EEC – deleted

94/32/EC

93/47/EEC

94/32/EC

95/34/EC

96/41/EC

97/45/EC

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
13	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA)	10 %		
14	Isopentyl-4-methoxycinnamate (Isoamyl p-Methoxycinnamate)	10 %		
15	2,4,6-Trianylino-(p-Carbo-2'-Ethylhexyl-1'Oxy)-1,3,5-Triazine (Octyl Triazone)	5 %		
16	Phenol,2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetra-methyl-1-(Trimethylsilyl)Oxy)-Disilo-xanyl)Propyl) (Drometrizole Trisiloxane)	15 %		
17	Benzoic acid, 4,4-(((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)1,3,5-triazine-2,4-diyl)diimino)bis-,bis-(2-ethylhexyl)ester)	10 %		
18	3-(4'-Methylbenzylidene)-d-1 camphor (4-Methylbenzylidene Camphor)	4 %		
19	3-Benzylidene camphor (3-Benzylidene Camphor)	2 %		
20	2-Ethylhexyl salicylate (Octyl-salicylate)	5 %		

98/62/EC

(¹) Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.

PART 2

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

Reference number	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
—					92/86/EEC – deleted
—					98/62/EC – deleted
—					92/86/EEC – deleted
5	2-Ethylhexyl 4-dimethylamino-benzoate	8 %			<u>30. 6. 1999</u> 98/62/EC
—					98/62/EEC – deleted
—					98/62/EEC – deleted
—					97/45/EC – deleted
—					92/86/EEC – deleted
17	2-Hydroxy-4-methoxybenzophenone-5 sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)	5 % (expressed as acid)			<u>30. 6. 1999</u> 98/62/EC
—					94/32/EC – deleted
—					98/62/EC – deleted
—					98/62/EC – deleted
—					94/32/EC – deleted
29	4-Isopropylbenzyl salicylate	4 %			<u>30. 6. 1999</u> 98/62/EC
—					93/47/EEC – deleted
—					98/62/EC – deleted
—					96/41/EC – deleted

89/174/EEC

ANNEX VIII

93/35/EEC

