

# COMMISSION OF THE EUROPEAN COMMUNITIES

SEC(90) 1985 final

Brussels, 29 October 1990

Proposal for a  
COUNCIL DIRECTIVE

on the approximation of the laws of the Member States  
relating to cosmetic products

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EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen, thus giving him new opportunities and the chance to make use of the specific rights it gives him.

This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules. For this reason a consolidation of rules that have frequently been amended is essential if Community law is to be clear and transparent.

2. In its resolution of 26 November 1974 concerning consolidation of its acts (1), the Council recommended that those of its acts which have been amended several times be assembled into a single text. It stressed that, in the interests of legal certainty, a genuine legislative consolidation, involving the repeal of earlier acts, should wherever possible be effected (as is being done in this case). It consequently invited the Commission to let it have proposals for consolidation and undertook to examine them "as quickly as possible, without bringing into question, during that consolidation, the substantive solutions contained in the consolidated texts".
3. By its decision of 1 April 1987 the Commission instructed its departments to produce a formal consolidated version of legislative instruments no later than after their tenth amendment, but made it clear that this was a minimum requirement, and that in the interests of clarity and of the ready comprehension of Community law, an effort should be made by each department to consolidate the instruments for which it is responsible at more frequent intervals.

The attached proposal for a consolidation of Council Directive 76/768/EEC applies the fundamental principles on which the Council, Parliament and the Commission agreed in 1974 and aims at legislative consolidation: the existing directives would be replaced by one new one, which would leave their substance untouched but would assemble them into a single text, with only the formal amendments required by the operation itself.

4. As in the past the text supplied here is collated from the original Directives as published in the Official Journal; the use of photocopies means that any improvements to the wording are immediately identifiable. The old numbering of the Articles has been retained for ease of reference, the new numbering being entered in the margin; Annex IX provides a concordance table relating the old system of numbering to the new. In order to preserve the dates for transposal of Directive 76/768/EEC and its successive amendments a new Annex VIII lists the deadline for implementation of each of the directives now being repealed.

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(1) OJ No C 20, 28.01.1975, p. 1.

**COUNCIL DIRECTIVE 76/768/EEC**

of 27 July 1976

on the approximation of the laws of the Member States  
relating to cosmetic products

(OJ No L 262 of 27.09.1976, p. 169)

amended by the Acts of Accession

of Greece (OJ No L 291 of 19.11.79, p.108)

of Spain and Portugal (OJ No L 302 of 15.11.85, p.218)

amended or adapted by the Directives

79/661/EEC of the Council (OJ No L 192 of 31.07.1979, p. 35)  
82/147/EEC of the Commission (OJ No L 63 of 06.03.1982, p. 26)  
82/368/EEC of the Council (OJ No L 167 of 15.06.1982, p. 1)  
83/191/EEC of the Commission (OJ No L 109 of 26.04.1983, p. 25)  
83/341/EEC of the Commission (OJ No L 188 of 13.07.1983, p. 15)  
83/496/EEC of the Commission (OJ No L 275 of 08.10.1983, p. 20)  
83/574/EEC of the Council (OJ No L 332 of 28.11.1983, p. 38)  
84/415/EEC of the Commission (OJ No L 228 of 25.08.1984, p. 31)  
85/391/EEC of the Commission (OJ No L 224 of 22.08.1985, p. 40)  
86/179/EEC of the Commission (OJ No L 138 of 24.05.1986, p. 40)  
86/199/EEC of the Commission (OJ No L 149 of 03.06.1986, p. 38)  
87/137/EEC of the Commission (OJ No L 56 of 26.02.1987, p. 20)  
88/233/EEC of the Commission (OJ No L 105 of 26.04.1988, p. 11)  
88/667/EEC of the Council (OJ No L 224 of 22.08.1985, p. 46)  
89/174/EEC of the Commission (OJ No L 64 of 08.03.1989, p. 10)  
89/679/EEC of the Council (OJ No L 398 of 30.12.1989, p. 25)  
90/121/EEC of the Commission (OJ No L 71 of 17.03.1990, p. 40)

Proposal for a  
COUNCIL DIRECTIVE

on the approximation of the laws of the Member States relating to cosmetic products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

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

Whereas Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (3), as last amended by Directive 90/121/EEC (4), has been amended several times and to a substantial extent; whereas for the sake of clarity the Directive should therefore be consolidated;

Whereas measures must be adopted with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

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;

1. 76/768/EEC

(1) OJ No C

(2) OJ No C

(3) OJ No L 262, 27.09.1976, p. 169.

(4) OJ No L 71, 17.03.1990, p. 40.

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;

2. 76/768/EEC

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;

3.

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;

4.

Whereas this Directive relates only to cosmetic products and not to pharmaceutical 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;

5.

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;

6.

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;

7.

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;

8.

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;

9.

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;

10.

Whereas, on the basis of the latest scientific and technical research, lists of substances authorized for use as preservatives and as ultra-violet filters have been drawn up;

2.

82/368/EEC 83/574/EEC  
(adapted)

Whereas, on the basis of the latest scientific and technical research available, certain provisionally permitted colouring agents, substances, preservatives or ultra-violet filters may be definitively permitted, while others must be definitively prohibited or be permitted for a further specific period;

Whereas the presence of traces of substances which cosmetic products must not contain according to Annex II to this Directive is technologically inevitable with correct manufacturing processes; whereas therefore certain provisions should be made in this connection;

11.

82/368/EEC

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,

11.

76/768/EEC

Whereas this Directive is without prejudice to the dates by which the Member States must comply with Directive 76/768/EEC and the successive amendments to it listed in Annex VIII,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. A 'cosmetic product' means any substance or preparation intended for placing 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 principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.

2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.

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.

76/768/EEC

88/667/EEC

*Article 2*

Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use.

*Article 3*

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.

76/768/EEC

*Article 4*

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; 88/667/EEC
  - (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; 82/368/EEC
  - (g) UV filters other than those listed in Part I of Annex VII; 83/574/EEC
  - (h) UV filters listed in Part I of Annex VII, beyond the limits and outside the conditions laid down therein. 83/574/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 complies with Article 2. 82/368/CEE



*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.

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:

- (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.

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, and 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, this information must appear on an enclosed leaflet, with abbreviated information on the container and the packaging referring the consumer to the information specified;

(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.

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.

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.

*Article 7*

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. Member States may, however, require that the particulars provided for in Article 6 (1) (b), (c) and (d) be expressed at least in their own national or official language or languages.

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

*Article 8*

1. In accordance with the procedure laid down in Article 14 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 amendments necessary for adapting Annexes II to VII to technical progress shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee for Cosmetology at the initiative of the Commission or of a Member State.

76/768/EEC

82/368/EEC.

*Article 8a*

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. Member States shall forward to the Commission and to the other Member States the next 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(a), 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 14 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

82/368/EEC

Article 9

1. A 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

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.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period to be laid down in each act to be adopted by the Council under this paragraph but which may in no case exceed three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Without prejudice to Article 5, 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 10

76/768/EEC

Article 11

Article 12

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.

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 11. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

Article 13

88/667/EEC

76/768/EEC

Article 14

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. Measures 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 15

Article 14

1. Member States shall take the measures necessary to comply with this Directive not later than the date listed for each Directive separately in Annex VIII. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of provisions of national law, whether laws, regulations or administrative provisions, which they adopt to comply with this Directive.

*Article 16*

Directive 76/768/EEC is hereby repealed.

References to the repealed Directive shall be construed as references to this Directive and are to be read in accordance with the correlation table set out in Annex IX.

*Article 15*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Council*

Article 17



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 make-up 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.

ANNEX II

LIST OF SUBSTANCES WHICH MUST NOT FORM  
PART OF THE COMPOSITION OF COSMETIC PRODUCTS

76/768/EEC

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. 2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts → 82/368/EEC
3. Deanol aceglumate\*
4. Spironolactone\*
5. [4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts → 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. Aconitum napellus L. (leaves, roots and galenical preparations)
12. Aconitine (principal alkaloid of Aconitum napellus L.) and its salts
13. Adonis vernalis L. and its preparations
14. Epinephrine\*
15. Rauwolfia serpentina 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. Sympathomimetic 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. 2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts → 82/368/EEC

\* 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.

30.	1,3-dimethylpentylamine and its salts	
31.	4-Aminosalicylic acid and its salts	
32.	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	
33.	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	
34.	Imperatorin (9-(3-methylbut-2-enyloxy)furo[3,2-g]chromen-7-one)	82/368/EEC
35.	Ammi majus and its galenical preparations	
36.	2,3-Dichloro-2-methylbutane	
37.	Substances with androgenic effect	
38.	Anthracene oil	
39.	Antibiotics	
40.	Antimony and its compounds	90/121/EEC
41.	Apocynum cannabinum L. and its preparations	76/768/EEC
42.	Apomorphine (R 5, 6, 6a, 7-tetrahydro-6-methyl-4H-dibenzo[de,g] quinoline-10,11-diol) and its salts	82/368/EEC
43.	Arsenic and its compounds	
44.	Atropa belladonna L. 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 (3) in Annex IV, Part 1.	83/191/EEC
47.	Benzene	76/768/EEC
48.	Benzimidazol-2(3H)-one	
49.	Benzazepines and benzodiazepines	
50.	1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts	82/368/EEC
51.	2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts	
52.	Isocarboxazid*	
53.	Bendroflumethiazide* and its derivatives	
54.	Beryllium and its compounds	
55.	Bromine, elemental	
56.	Bretylum 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*	76/768/EEC
66.	Carbutamide*	
67.	Phenylbutazone*	
68.	Cadmium and its compounds	
69.	Cantharides, <i>Cantharis vesicatoria</i>	
70.	(1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)	
71.	Phenprobamate*	
72.	Nitroderivatives of carbazole	
73.	Carbon disulphide	82/368/EEC
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.	Diphenoxylate* hydrochloride	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.	N,N-bis (2-chloroethyl) methylamine N-oxide and its salts	82/368/EEC
87.	Chlormethine* and its salts	
88.	Cyclophosphamide* and its salts	
89.	Mannomustine* and its salts	
90.	Butanilicaine* and its salts	
91.	Chlormezanone*	
92.	Triparanol*	82/368/EEC
93.	2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan 1,3-dione (chlorophacinone - ISO)	82/368/EEC
94.	Chlorphenoxamine*	
95.	Phenaglycodol*	
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	76/768/EEC
104.	Colchicum autumnale L. and its galenical preparations	
105.	Convallatoxin	
106.	Anamirta cocculus K. (fruit)	
107.	Croton tiglium (oil)	
108.	1-Butyl-3-(N-crotonoylsulphanilyl)urea	
109.	Curare and curarine	
110.	Synthetic curarizants	
111.	Hydrogen cyanide and its salts	
112.	2- $\alpha$ -Cyclohexylbenzyl(N,N,N',N',-tetraethyl)trimethylenediamine (phenetamine)	82/368/EEC
113.	Cyclomenol* and its salts	
114.	Sodium hexacyclonate*	
115.	Hexapropymate*	
116.	Dextropropoxyphene*	
117.	O,O'-Diacetyl-N-allyl-N-normorphine	82/368/EEC
118.	Pipazetate* and its salts	
119.	5-( $\alpha$ beta-Dibromophenethyl)-5-methylhydantoin	
120.	N,N'-Pentamethylenebis (trimethylammonium) salts, e.g. pentamethonium bromide*	82/368/EEC
121.	N,N'-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, e.g. azamethonium bromide*	
122.	Cyclarbamate*	
123.	Clofenotane*; DDT (ISO)	
124.	N,N'-Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*	82/368/EEC
125.	Dichloroethanes (ethylene chlorides)	
126.	Dichloroethylenes (acetylene chlorides)	
127.	Lysergide* and its salts	
128.	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	82/368/EEC
129.	Cinchocaine* and its salts	
130.	3-Diethylaminopropyl cinnamate	
131.	O,O'-Diethyl O-4-nitrophenyl phosphorothioate (parathion - ISO)	82/368/EEC
132.	[Oxalylbisiminoethylene]bis[(o-chlorobenzyl)diethylammonium] salts, e.g. ambenomium chloride*	82/368/EEC
133.	Methpyrlylon* and its salts	
134.	Digitaline and all heterosides of Digitalis purpurea L.	
135.	7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl]theophylline (xanthinol)	
136.	Dioxethedrin* and its salts	
137.	Piprocuarium*	
138.	Propyphenazone*	

139.	Tetrabenazine* and its salts	
140.	Captodiame*	
141.	Mefecloazine* and its salts	76/768/EEC
142.	Dimethylamine	
143.	1,1-Bis(dimethylaminomethyl)propyl benzoate (amydracaine, alypine) and its salts	
144.	Methapyrilene* and its salts	→ 82/368/EEC
145.	Metamfepramone* and its salts	
146.	Amitriptyline* and its salts	
147.	Metformin* and its salts	
148.	Isosorbide dinitrate*	
149.	Malononitrile	
150.	Succinonitrile	
151.	Dinitrophenol isomers	
152.	Inproquone*	
153.	Dimevamide* and its salts	
154.	Diphenylpyraline* and its salts	
155.	Sulfinpyrazone*	
156.	N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e.g. isopropamide iodide*	→ 82/368/EEC
157.	Benactyzine*	
158.	Benzatropine* and its salts	
159.	Cyclizine* and its salts	
160.	5,5-Diphenyl-4-imidazolidone	
161.	Probenecid*	→ 82/368/EEC
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 Annex VII, Part 2,	→ 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.	Oxpheperidine* and its salts	
173.	Ethoheptazine* and its salts	
174.	Metheptazine* and its salts	

175.	Methylphenidate* and its salts	
176.	Doxylamine* and its salts	76/768/EEC
177.	Tolboxane*	
[ 178.	4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol	85/391/EEC
179.	Parethoxycaine* and its salts	
180.	Fenozolone*	76/768/EEC
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*	
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
195.	1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)	76/768/EEC
196.	(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-dimethanonaphthalene (endrin - ISO)	82/368/EEC
197.	Hexachloroethane	
198.	(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)	
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.	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid	82/368/EEC
205.	Methocarbamol*	
206.	Propatynitrate*	
207.	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene)dicoumarin	82/368/EEC
208.	Fenadiazole*	
209.	Nitroxoline* and its salts	

210.	Hyoscyamine, its salts and derivatives	
211.	Hyoscyamus niger L. (leaves, seeds, powder and galenical preparations)	76/768/EEC
212.	Pemoline* and its salts	
213.	Iodine	
214.	Decamethylenebis (trimethylammonium) salts, e.g. decamethonium bromide	82/368/EEC
215.	Ipecacuanha (Cephaelis ipecacuanha Brot. and related species) (roots, powder and galenical preparations)	
216.	(2-Isopropylpent-4-enoyl)urea (apronalide)	
217.	alpha-Santonin [(3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto [1,2-b] furan-2,8-dione]	82/368/EEC
218.	Lobelia inflata L. and its galenical preparations	
219.	Lobeline* and its salts	
220.	Barbiturates	
[221.	Mercury and its compounds, except those special cases included in Annexes V and VI, Part 1.	86/199/EEC
222.	3,4,5-Trimethoxyphenethylamine and its salts	
223.	Metaldehyde	
224.	2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts	76/768/EEC
225.	Coumetarol*	
226.	Dextromethorphan* and its salts	
227.	2-Methylheptylamine and its salts	
228.	Isometheptene* and its salts	
229.	Mecamylamine*	
230.	Guaifenesin*	
231.	Dicoumarol*	
232.	Phenmetrazine*, its derivatives and salts	
233.	Thiamazole*	
234.	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H, pyrano[3,2-c]-[1] benzopyran-5-one (cyclocoumarol)	82/368/EEC
235.	Carisoprodal*	
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.	3-(1-Naphthyl)-4-hydroxycoumarin	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	76/768/EEC
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	
259.	Guanethidine* and its salts	
260.	Oestrogens	
261.	Oleandrin	
262.	Chlortalidone*	
263.	Pelletierine and its salts	
264.	Pentachloroethane	
265.	Pentaerithryl tetranitrate*	
266.	Petrichloral*	
267.	Octamylamine* and its salts	
268.	Picric acid	82/368/EEC
269.	Phenacemide*	
270.	Difenclozazine*	76/768/EEC
271.	2-Phenylindan-1,3-dione (phenindione)	→ 82/368/EEC
272.	Ethylphenacemide*	
273.	Phenprocoumon*	
274.	Fenramidol*	
275.	Triamterene* and its salts	
276.	Tetraethyl pyrophosphate; TEPP (ISO)	→ 82/368/EEC
277.	Tritolyl phosphate	
278.	Psilocybine*	
279.	Phosphorus and metal phosphides	
280.	Thalidomide* and its salts	
281.	Physostigma venenosum Balf	
282.	Picrotoxin	
283.	Pilocarpine and its salts	

284.	alpha-Piperidin-2-ylbenzyl acetate laevorotatory threoform (levopropacetoperane) and its salts	76/768/EEC
285.	Pipradrol* and its salts	82/368/EEC
286.	Azacyclonol* and its salts	
287.	Bietamiverine*	
288.	Butopirine* and its salts	
[ 289.	Lead and its compounds, with the exception of that mentioned in Annex III, N° 55 under the conditions stated	90/121/EEC
290.	Coniine	76/768/EEC
291.	Prunus laurocerasus L. ('cherry laurel water')	
292.	Metyrapone*	
293.	Radioactive substances (1)	
294.	Juniperus sabina L. (leaves, essential oil and galenical preparations)	
295.	Hyoscine, its salts and derivatives	85/391/EEC
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	
298.	Solanum nigrum L. and its galenical preparations	76/768/EEC
299.	Sparteine and its salts	82/368/EEC
300.	Glucocorticoids	
301.	Datura stramonium L. and its galenical preparations	
302.	Strophantines, their aglucones and their respective derivatives	
303.	Strophantus species and their galenical preparations	
304.	Strychnine and its salts	
305.	Strychnos 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.	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH <sub>2</sub> groups) and their salts	
308.	Sultiame*	
309.	Neodymium and its salts	
310.	Thiotepa*	
311.	Pilocarpus jaborandi Holmes and its galenical preparations	
312.	Tellurium and its compounds	

(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).

313.	Xylometazoline* and its salts	82/368/EEC
314.	Tetrachloroethylene	
315.	Carbon tetrachloride	76/768/EEC
316.	Hexaethyl tetraphosphate	
317.	Thallium and its compounds	
318.	Thevetia nerifolia 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.	Mephesisin* and its esters	
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)	76/768/EEC
324.	Tranlycypromine* and its salts	
325.	Trichloronitromethane (chloropicrine)	
326.	2,2,2-Tribromoethanol (tribromoethyl alcohol)	
327.	Trichlormethine* and its salts	
328.	Tretamine*	
329.	Gallamine triethiodide*	
330.	Urginea scilla Stern. and its galenical preparations.	
331.	Veratrine, its salts and galenical preparations.	
332.	Schoenocaulon officinale Lind. (seeds and galenical preparations)	
[333.	Veratrum Spp. and their preparations	84/415/EEC
334.	Vinyl chloride monomer	
335.	Ergocalciferol* and cholecalciferol (vitamins D2 and D3)	76/768/EEC
336.	Salts of O-alkyldithiocarbonic acids	
337.	Yohimbine 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.	Pyrethrum album L. and its galenical preparations	
346.	2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyl dimethylamine maleate	82/368/EEC
347.	Tripelennamine*	

348.	Tetrachlorosalicylanilides	
349.	Dichlorosalicylanilides	
350.	Tetrabromosalicylanilides	76/768/EEC
351.	Dibromosalicylanilides	
352.	Bithionol*	
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.	Furo[3,2-g]chromen-7-one and its alkyl-substituted derivatives (e.g. trioxysalan* and 8-methoxypsoralen), except for normal content in natural essences used	82/368/EEC
359.	Oil from the seeds of <i>Laurus nobilis</i> L.	
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 dihydroiodide	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.	o-phenylenediamine and its salts	83/341/EEC
[ 364.	4-methyl-m-phenylenediamine and its salts	
[ 365.	Aristolochic acid and its salts	84/415/EEC
[ 366.	Chloroform	86/179/EEC
[ 367.	2,3,7,8-Tetrachlorodibenzo-p-dioxin	88/233/EEC
[ 368.	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	86/179/EEC
[ 369.	Pyrithione sodium (INNM)	
(a) 370.	N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)	87/137/EEC
(a) 371.	2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)	
(a) 372.	6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (Minoxidil) and its salts and derivatives.	
373.	3,4',5-Tribromosalicylanide (Tribromsalan)	
374.	<i>Phytolacca</i> spp. and their preparations	88/233/EEC
375.	Tretinoin* (retinoic acid and its salts)	
376.	1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole - CI 76050) and their salts	90/121/EEC
377.	1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and their salts	
378.	Colouring agent CI 12140	

379.	Colouring agent CI 26105	
380.	Colouring agent CI 42555	88/233/EEC
	Colouring agent CI 42555-1	
	Colouring agent CI 42555-2	
(c) 381.	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))	89/174/EEC
(c) 382.	Benzoyl peroxide	
(c) 383.	2-Amino-4-nitrophenol	
(c) 384.	2-Amino-5-nitrophenol	
d) 385.	11 $\alpha$ -Hydroxypregn-4-ene-3,20-dione and its esters	90/121/EEC
d) 386.	Colouring agent CI 42640	
d) 387.	Colouring agent CI 13065	
d) 388.	Colouring agent CI 42535	
d) 389.	Colouring agent CI 61554	
d) 390.	Antiandrogens with steroid structure	
d) 391.	Zirconium and its compounds, with the exception of the complexes under reference N° 50 in Annex III (Part 1) and of Zirconium lakes, salts and pigments of colouring agents listed with reference N° 3 in Annexe IV (Part 1)	
d) 392.	Thyrothricine	
d) 393.	Acetonitrile	
d) 394.	Tetrahydrozoline and its salts	

	Latest permitted date of manufacture and importation	Latest permitted date of sale to endconsumer
a)		31.12.1990
c)		31.12.1990
d)	31.12.1990	31.12.1991

## 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

82/368/EEC

For the substances marked with  $\triangle$  see list at the end of the annex.

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
△ 2a	Thioglycollic acid and its salts	<p>(a) Hair waving or straightening products :</p> <ul style="list-style-type: none"> <li>— general use</li> <li>— professional use</li> </ul> <p>(b) Depilatories</p> <p>(c) Other hair-care products which are removed after application</p>	<ul style="list-style-type: none"> <li>— 8 % ready for use pH 7 to 9,5</li> <li>— 11 % ready for use pH 7 to 9,5</li> <li>— 5 % ready for use pH 7 to 12,7</li> <li>— 2 % ready for use pH 7 to 9,5</li> </ul> <p>The abovementioned percentages are calculated as thioglycollic acid</p>	<p>(a) (b) (c) :</p> <p>The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences :</p> <ul style="list-style-type: none"> <li>— Avoid contact with eyes</li> <li>— In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice</li> <li>— Wear suitable gloves (a) and (c) only</li> </ul>	<p>(a) :</p> <ul style="list-style-type: none"> <li>— Contains thioglycolate</li> <li>— Follow the instructions</li> <li>— Keep out of reach of children</li> <li>— For professional use only</li> </ul> <p>(b) and (c) :</p> <ul style="list-style-type: none"> <li>— Contains thioglycolate</li> <li>— Follow the instructions</li> <li>— Keep out of reach of children</li> </ul>
2b	Thioglycollic acid esters	<p>Hair waving or straightening products :</p> <ul style="list-style-type: none"> <li>— general use</li> <li>— professional use</li> </ul>	<ul style="list-style-type: none"> <li>— 8 % ready for use pH 6 to 9,5</li> <li>— 11 % ready for use pH 6 to 9,5</li> </ul> <p>The abovementioned percentages are calculated as thioglycollic acid</p>	<p>The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences :</p> <ul style="list-style-type: none"> <li>— May cause sensitization in the event of skin contact</li> <li>— Avoid contact with eyes</li> <li>— In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice</li> <li>— Wear suitable gloves</li> </ul>	<ul style="list-style-type: none"> <li>— Contains thioglycolate</li> <li>— Follow the instructions</li> <li>— Keep out of reach of children</li> <li>— For professional use only</li> </ul>
3	Oxalic acid, its esters and alkaline salts	Hair care products	5 %		For professional use only


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	
4	Ammonia		6 % calculated as NH <sub>3</sub>		Above 2 %: contains ammonia	82/368/EEC
5	Tosylchloramide sodium (*)		0.2 %			
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5 % (b) 3 %			
7	Dichloromethane		35 % (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 %)	0.2 % as maximum impurity content		
8	m- and p-phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-phenylenediamines (1)	Oxidizing colouring agents for hair dyeing (a) general use  (b) professional use	6 % calculated as free base		(a) Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows  (b) For professional use only Contains phenylenediamines Can cause an allergic reaction. Sensitivity test advisable before use	83/341/EEC

(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.

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
9	Methylphenylenediamines, their N-substituted derivatives and their salts (1) with the exception of substance No. 364 in Annex II.	Oxidizing colouring agents for hair dyeing (a) general use  (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows  (b) For professional use only. Contains phenylenediamines Can cause an allergic reaction. Sensitivity test advisable before use
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. Sensitivity test advisable before use Contains diaminophenols. Do not use to dye eyelashes or eyebrows  (b) For professional use only. Contains diaminophenols Can cause allergic reaction. Sensitivity test advisable before use
 11	Dichlorophen (*)		0.5 %		Contains dichlorophen

83/341/EEC

82/368/EEC

87/137/EEC

(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.

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	
12	Hydrogen peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations	12 % of H <sub>2</sub> O <sub>2</sub> (40 volumes) 4 % of H <sub>2</sub> O <sub>2</sub> 2 % of H <sub>2</sub> O <sub>2</sub>		(a) (b) (c) Contains hydrogen peroxide Avoid contact with eyes Rinse eyes immediately if product comes into contact with them	84/415/EEC
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde <sup>(1)</sup>	82/368/EEC
14	Hydroquinone (2)  Hydroquinone	(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 eyelashes 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	84/415/EEC

(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 2.

(2) Only if the concentration exceeds 0.05 %.

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	
					<ul style="list-style-type: none"> <li>- Avoid contact with the eyes</li> <li>- Apply to small areas</li> <li>- If irritation develops discontinue use</li> <li>- Do not use on children under the age of 12</li> </ul>

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
15	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 (1)  (b) 1. 2 % by weight (1)  2. 4.5 % by weight (1)  (c) up to pH 12.7  (d) up to pH 11		(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
16	$\alpha$ -naphthol	Colouring agent for hair dyeing	0.5 %		Contains $\alpha$ -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

(1) The sum of the two hydroxides expressed by weight as sodium hydroxide.

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
20	Pyrogallol (1)	Oxidizing colouring agent for hair dyeing (a) general use  (b) professional use	5 %		(a) Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains pyrogallol  (b) For professional use only. Contains pyrogallol. Rinse eyes immediately if product comes into contact with them
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 (1)	(a) Oxidizing colouring agent for hair dyeing 1. general use	(a) 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

82/368/EEC

(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 2.

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
22 (cont'd)		2. professional use  (b) Hair lotions and shampoos	(b) 0.5 %		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 ≤ 12.7  (b) 6 % calculated as sulphur pH ≤ 12.7		(a) Keep out of reach of children. Avoid contact with eyes  (b) Keep out of reach of children. Avoid contact with eyes
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrithione		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	Ammonium 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

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
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

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
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	NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride	Ditto	0.15 % Ditto		Contains NN'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

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
43	Magnesium fluorosilicate	Ditto	0.15 % Ditto		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			
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

82/368/EEC

86/179/EEC

82/368/EEC

83/191/EEC

84/415/EEC

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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	
49	Selenium disulphide	Antidandruff shampoos	1 %		<ul style="list-style-type: none"> <li>— Contains selenium disulphide</li> <li>— Avoid contact with eyes or damaged skin</li> </ul>	85/391/EEC
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr_y(OH)_zCl_n$ and the aluminium zirconium chloride hydroxide glycine complexes	Antiperspirants	20 % as anhydrous aluminium zirconium chloride hydroxide 5,4 % as zirconium	<ol style="list-style-type: none"> <li>1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between two and 10</li> <li>2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0,9 and 2,1</li> <li>3. Prohibited in aerosol dispensers (sprays)</li> </ol>	Do not apply to irritated or damaged skin	
△ 51	Quinolin-8-ol and bis (8-hydroxyquinolium) sulphate	<p>Stabilizer for hydrogen peroxide in rinse-off hair-care preparations</p> <p>Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations</p>	<p>0,3 % calculated as base</p> <p>0,03 % calculated as base'</p>			88/233/EEC
△ 52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % of ethanol and isopropyl alcohol'			87/137/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	
△ 53	Etidronic acid and its salts (1-hydroxyethylidene-di-phosphonic acid and its salts)	(a) Hair-care (b) Soap	1,5 % 0,2 % } expressed as etidronic acid		
△ 54	1-Phenoxy-propan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %	As a preservative, see Annex VI, Part 1, No 43	
△ 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 moustasches. If irritation develops, discontinue use.

88/233/EEC

90/121/EEC

## ANNEX III

## 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	
△ 1	Quinolin-8-ol and bis (8-hydroxy-quinolium) sulphate	(a) Preparations for skin hygiene not rinsed off after use (b) Foot hygiene preparations not rinsed off after use (c) Mouth hygiene products	0,02 % calculated as base  0,04 % calculated as base  0,01 % calculated as base		(a) (b) (c) Contains quinolin-8-ol	31.12.1990	89/174/EEC
△ 2	1,1,1-Trichloroethane (methyl chloroform)	Aerosol spray	35 % When mixed with dichloromethane, total concentration must not exceed 35 %		Do not spray on a naked flame or any incandescent material	31.12.1990	86/199/EEC 90/121/EEC
△ 4	2,2'-Dithiobis (pyridine 1-oxide), addition product with magnesium sulphate trihydrate	Only for hair-care products rinse off	1 %			31.12.1990	90/121/EEC

TABLE OF LATEST PERMITTED DATES FOR THE PLACING ON THE MARKET AND SALE TO ENDCONSUMER OF COSMETIC PRODUCTS CONTAINING SUBSTANCES LISTED IN ANNEX III, COLUMN a) AND WHICH DO NOT COMPLY WITH THE DIRECTIVE

Reference number	Latest permitted date of manufacture and importation	Latest permitted date of sale to endconsumer
a	b	c
Annex III, Part 1		
N° 2		31/12/1991
N° 11		31/12/1990
N° 51		31/12/1991
N° 52		31/12/1990
N° 53		31/12/1991
N° 54		31/12/1991
N° 55	31/12/1991	31/12/1993
Annex III, Part 2		
N° 1	31/12/1990	31/12/1992
N° 2	31/12/1991	31/12/1993
N° 4	31/12/1991	31/12/1993

ANNEX IV

86/179/EEC

PART 1

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 denomination	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		
12075 (3)	Orange	X				
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	
13015	Yellow	X				E 105
					X	
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122

For the substances marked with  $\Delta$  see list at the end of the annex.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)		
		1	2	3	4			
14815	Red	X				E 125	86/179/EEC	
15510 <sup>(3)</sup>	Orange		X					
15525	Red	X						
15580	Red	X						
15585 <sup>(3)</sup>	Red		X					
15620	Red				X			
15630 <sup>(3)</sup>	Red	X				3 % maximum concentration in the finished product		
15800	Red			X				
15850 <sup>(3)</sup>	Red	X						
15865 <sup>(3)</sup>	Red	X						
15880	Red	X						
15980	Orange	X				E 111		
15985 <sup>(3)</sup>	Yellow	X				E 110		
16035	Red	X						
16185	Red	X				E 123		
16230	Orange			X				
16255 <sup>(3)</sup>	Red	X				E 124		
16290	Red	X				E 126		
17200 <sup>(3)</sup>	Red	X						→ 90/121/EEC
18050	Red			X				90/121/EEC
18130	Red				X			
18690	Yellow				X			
18736	Red				X			
18820	Yellow				X			
18965	Yellow	X						
19140 <sup>(3)</sup>	Yellow	X						
20040	Yellow				X	E 102 maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm		
20170	Orange			X				
20470	Black				X			
21100	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm		
21108	Yellow				X	ditto		
21230	Yellow			X				
24790	Red				X			
27290 <sup>(3)</sup>	Red				X			
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 g		
△ 42045	Blue			X			→ 90/121/EEC	
42051 <sup>(3)</sup>	Blue	X				E 131		
42053	Green	X						
42080	Blue				X			




Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
42090	Blue	X				5 ppm maximum concentration in the finished product
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	
42735	Blue			X		E 142
44045	Blue			X		
44090	Green	X				E 142
45100	Red				X	
45170 (3)	Red	X				E 142
45170:1			X			
45190	Violet				X	6% maximum concentration in the finished product
45220	Red				X	
45350	Yellow	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
45370 (3)	Orange	X				
45380 (3)	Red	X				ditto
45396	Orange	X				
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
45410 (3)	Red	X				
45425	Red	X				ditto
45430 (3)	Red	X				
47000	Yellow			X		E 104
47005	Yellow	X				
50325	Violet				X	E 104
50420	Black			X		
51319	Violet				X	E 104
58000	Red	X				
59040	Green			X		E 104
60724	Violet				X	
60725	Violet	X				E 104
60730	Violet			X		
61565	Green	X				E 104
61570	Green	X				
61585	Blue				X	E 104
62045	Blue				X	
69800	Blue	X				E 130
69825	Blue	X				
71105	Orange			X		E 130
73000	Blue	X				
73015	Blue	X				E 132

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Colour index number or denomination	Colour	Field of application				Other limitations and requirements (?)	
		1	2	3	4		
73360	Red	X					
73385	Violet	X					
73900	Violet				X	see Annex IV, Part 2	
73915	Red				X		
74100	Blue				X		
74160	Blue	X					
74180	Blue				X	see Annex IV, Part 2	
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	
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 ions	87/137/EEC
△ 77289	Green	X				free from chromate ions	
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 c	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)	
		1	2	3	4		
Beetroot red	Red	X				E 162 E 163	86/179/EEC
Anthocyanins	Red	X					
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 food-stuffs 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.

ANNEX IV

PART 2

86/179/EEC

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 (2)	Authorization valid until
		1	2	3	4		
△ 26100	Red	X				31.12.1990	
△ 73900	Violet			X	see Annex IV, Part 1	31.12.1990	
△ 74180	Blue			X	see Annex IV, Part 1	31.12.1991	
Solvent yellow △ 98	Yellow			X	Only in nail care preparations max. 0.5 % in the final product	31.12.1991	

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90/121/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.

TABLE OF LATEST PERMITTED DATES FOR THE PLACING ON THE MARKET AND SALE TO ENDCONSUMER OF COSMETIC PRODUCTS CONTAINING SUBSTANCES LISTED IN ANNEX IV, COLUMN a) AND WHICH DO NOT COMPLY WITH THE DIRECTIVE

Reference number	Latest permitted date of manufacture and importation	Latest permitted date of sale to endconsumer
a	b	c
Annex IV, Part 1		
77288		31/12/1990
77289		31/12/1990
Acid Red 195		31/12/1991
42045	31/12/1991	31/12/1993
44045	31/12/1991	31/12/1993
Annex IV, Part 2		
26100	31/12/1991	31/12/1993
73900	31/12/1991	31/12/1993
74180	31/12/1991	31/12/1993
Solvent Yellow 98	31/12/1991	31/12/1993

ANNEX V

LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THE DIRECTIVE

76/768/EEC

5. Strontium and its compounds, with the exception of strontium sulphide under the conditions laid down in Annex III, Part 1, and of strontium salts, lakes and pigments of the colouring agents listed with reference (3) in Annex IV, Part 1.

83/191/EEC

7. Thiomersal\* and phenylmercuric compounds (for use as preservatives in concentrated shampoos and creams containing non-ionic emulsifiers which render other preservatives ineffective; maximum concentration 0.003% calculated as Hg).
8. Lidocaine\*.

76/768/EEC

ANNEX VI

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN

86/199/EEC

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 %.

For the substances marked with  $\Delta$  see list at the end of the annex.

## PART 1

86/199/EEC

## 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 (†)
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) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
7	Biphenyl-2-ol (o-phenylphenol) and its salts (†)	0,2 % expressed as the phenol		
8	Pyrrhione 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 <sub>2</sub>		
10	Sodium iodate	0,1 %	Rinse-off products only	

(†) 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
11	Chlorobutanol (INN)	0,5 %	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters (†)	0,4 % (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 (†)	0,5 % (acid)		
15	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (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)		
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 %	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol (†)	0,15 %		
23	Triclocarban (INN) (†)	0,2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene < 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	

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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
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'-methylenediurea ("Imidazolidinyl urea") (†)	0,6 %		
28	Poly (1-hexamethylenebiguanide hydrochloride) (†)	0,3 %		
29	2-Phenoxyethanol (†)	1 %		
30	Hexamethylenetetramine (†) (methenamine) (INN)	0,15 %		
31	Methenamine 3-chloroallylochloride (INN)	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 %		
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 %		Not to be used in cosmetic sunscreen products
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		

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→89/174/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
△ 40	2-Benzyl-4-chlorophenol (chlorophene)	0,2 %		
△ 41	2-Chloroacetamide	0,3 %		Contains chloroacetamide
△ 42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3 % expressed as chlorhexidine		
△ 43	1-Phenoxypropan-2-ol	1,0 %	Only for rinse-off products	

87/137/EEC

88/233/EEC

## PART 2

## LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitation and requirements	Conditions of use and warnings which must be printed on the label	Allowed until	
a	b	c	d	e	f	
△ 2	Chlorphenesin (INN)	0,3 %			31.12.1990	86/199/EEC 90/121/EEC 88/233/EEC
△ 4	Alkyl (C12-C22) trimethyl-ammonium bromide and chloride (including Cetrimonium bromide (INN) (†))	0,1 %			31.12.1990	90/121/EEC
△ 6	4,4-Dimethyl-1,3-oxazolidine	0,1 %	Rinse-off products only. The pH of the finished product shall not be lower than 6		31.12.1990	90/121/EEC
△ 15	Benzethonium chloride (INN) (†)	0,1 %	Prohibited in the products intended to come into contact with mucous membranes		31.12.1990	90/121/EEC
△ 16	Benzalkonium chloride (INN), bromide and saccharinate (†)	0,25 %			31.12.1990	90/121/EEC
△ 17	1-[1,3-Bis (hydroxymethyl)-2,5-dioxoimidazolidin-1-yl]-1,3-bis (hydroxymethyl) urea	0,5 %			31.12.1990	90/121/EEC
△ 20	Hexamidine (INN) and its salts (including isethionate and 4-hydroxybenzoate) (†)	0,1 %			31.12.1990	90/121/EEC
21 △	Benzylhemiformal (a 1:1 mixture of benzyloxymethanol and (benzyloxymethoxy) methanol)	0,2%			31.12.1990	90/121/EEC
△ 26	Glutaraldehyde	0,1 %	Prohibited in aerosols (sprays)	Contains glutaraldehyde where the glutaraldehyde concentration in the finished product exceeds 0,05 %	31.12.1991	89/174/EEC
27	3-Decyloxy-2-hydroxy-1-amino propane-hydrochloride (Decominol) (INN)	0.5 %			31.12.1990	90/121/EEC

TABLE OF LATEST PERMITTED DATES FOR THE PLACING ON THE MARKET AND SALE TO ENDCONSUMER OF COSMETIC PRODUCTS CONTAINING SUBSTANCES LISTED IN ANNEX VI, COLUMN a) AND WHICH DO NOT COMPLY WITH THE DIRECTIVE

Reference number	Latest permitted date of manufacture and importation	Latest permitted date of sale to endconsumer
a	b	c
Annex VI, Part 1		
N° 39	31/12/1990	31/12/1992
N° 40		31/12/1990
N° 41		31/12/1991
N° 42		31/12/1991
N° 43		31/12/1991
Annex VI, Part 2		
N° 2	31/12/1991	31/12/1993
N° 4	31/12/1991	31/12/1993
N° 6	31/12/1991	31/12/1993
N° 15	31/12/1991	31/12/1993
N° 16	31/12/1991	31/12/1993
N° 17	31/12/1991	31/12/1993
N° 20	31/12/1991	31/12/1993
N° 21	31/12/1991	31/12/1993
N° 26	31/12/1990	31/12/1992
N° 27	31/12/1991	31/12/1993

ANNEX VII

83/574/EEC

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 I

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	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate	6 %		
3	Homosalate (INN)	10 %		
4	Oxybenzone (INN)	10 %		Contains oxybenzone (!)
5	3-Imidazol-4-ylacrylic acid and its ethyl ester	2 % (expressed as acid)		
6	2-phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (expressed as acid)		

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

For the substances marked with  $\Delta$  see List at the end of the annex.

ANNEX VII

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
1	N-Propoxylated ethyl-4-aminobenzoate (mixed isomers)	5 %			31. 12. 1991
2	Ethoxylated ethyl-4-aminobenzoate	10 %			31. 12. 1991
4	Glycerol 1-(4-aminobenzoate)	5 %	Free from benzocaine (INN)		31. 12. 1991
5	2-Ethylhexyl 4-dimethylaminobenzoate	8 %			31. 12. 1991
6	2-Ethylhexyl salicylate	5 %			31. 12. 1991
12	Isopentyl-4-methoxycinnamate (mixed isomers)	10 %			31. 12. 1991
13	2-Ethylhexyl 4-methoxycinnamate	10 %			31. 12. 1991
16	2-Hydroxy-4-methoxy-4'-methylbenzophenone (mexenonc)	4 %		Contains mexenone (*)	31. 12. 1991
17	2-Hydroxy-4-methoxybenzophenone-5 sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)	5 % (expressed as acid)			31. 12. 1991
24	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6 % (expressed as acid)			31. 12. 1991
25	3-(4'-Methylbenzylidene)-d-1-camphor	6 %			31. 12. 1991
26	3-Benzylidene camphor	6 %			31. 12. 1991
28	4-Isopropyl-dibenzoylmethane	5 %			31. 12. 1991
29	4-Isopropylbenzyl salicylate	4 %			31. 12. 1991
31	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5 %			31. 12. 1991
32	2,4,6-Triamino-(p-carbo-2'-ethylhexyl-1'-oxi)-1,3,5-triazine	5 %			31. 12. 1991

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

TABLE OF LATEST PERMITTED DATES FOR THE PLACING ON THE MARKET AND SALE TO ENDCONSUMER OF COSMETIC PRODUCTS CONTAINING SUBSTANCES LISTED IN ANNEX VII, COLUMN a) AND WHICH DO NOT COMPLY WITH THE DIRECTIVE

Reference number	Latest permitted date of manufacture and importation	Latest permitted date of sale to endconsumer
a	b	c
Annex VII, Part 2	31/12/1990	31/12/1992



ANNEX VIII

LIST OF DIRECTIVES AMENDING DIRECTIVE 76/768/EEC  
AND THEIR DATES OF IMPLEMENTATION BY THE MEMBER STATES

	<u>date of implementation</u>
Council Directive 76/768/EEC of 27 July 1976..... (OJ L 262 of 27 September 1976, page 169)	30 January 1978
<u>amended by:</u>	
Council Directive 79/661/EEC of 24 July 1979 (OJ L 192 of 31 July 1979, page 35)	26 July 1979
Commission Directive 82/147/EEC of 11 February 1982..... (OJ L 63 of 6 March 1982, page 26)	31 December 1982
Council Directive 82/368/EEC of 17 May 1982..... (OJ L 167 of 15 June 1982, page 1)	31 December 1983
2nd Commission Directive 83/191/EEC of 30 March 1983..... (OJ L 109 of 26 April 1983, page 25)	31 December 1984
3rd Commission Directive 83/341/EEC of 29 June 1983..... (OJ L 188 of 13 July 1983, page 15)	31 December 1984
4th Commission Directive 83/496/EEC of 22 September 1983.. (OJ L 275 of 8 October 1983, page 20)	31 December 1984
Council Directive 83/574/EEC of 26 October 1983..... (OJ L 332 of 28 November 1983, page 38)	31 December 1984
5th Commission Directive 84/415/EEC of 18 July 1984..... (OJ L 228 of 25 August 1984, page 31)	31 December 1985
6th Commission Directive 85/391/EEC of 16 July 1985..... (OJ L 224 of 22 August 1985, page 40)	31 December 1986
7th Commission Directive 86/179/EEC of 28 February 1986... (OJ L 138 of 24 May 1986, page 40)	31 December 1986
8th Commission Directive 86/199/EEC of 26 March 1986..... (OJ L 149 of 3 June 1986, page 38)	31 December 1986
9th Commission Directive 87/137/EEC of 2 February 1987.... (OJ L 56 of 26 February 1987, page 20)	31 December 1987
10th Commission Directive 88/233/EEC of 2 March 1988..... (OJ L 105 of 26 April 1988, page 11)	30 September 1988

date of implementation

Council Directive 88/667/EEC of 21 December 1988.....31 December 1989  
(OJ L 328 of 31 December 1988, page 46)

11th Commission Directive 89/174/EEC of 21 February 1989...31 December 1989  
(OJ L 64 of 8 March 1989, page 10)

Council Directive 89/679/EEC of 21 December 1989.....21 December 1989  
(OJ L 398 of 30 December 1989, page 25)

12th Commission Directive 90/121/EEC of 20 february 1990....31 December 1990  
(OJ L 71 of 17 March 1990, page 40)

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Directive 76/768/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 8 (a)	Article 9
Article 9	Article 10
Article 10	Article 11
Article 11	Article 12
Article 12	Article 13
Article 13	Article 14
Article 14	Article 15
Article -	Article 16
Article 15	Article 17

COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT

SWISS LEGATION

DEPT. OF ECON. AFF.

Consolidated version of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

This proposal from the Commission meets the wish expressed many times by the Member States and the European Parliament that measures should be taken to speed up the codifying and simplifying of Community law. The proposal contains no new provisions, and therefore has no particular impact on SMEs; but it should be noted because its aim, the transparency of Community law, is in the long-term interests of SMEs.