The rules governing cosmetic products
in the European Union

Volume 1

Cosmetics legislation

Cosmetic products

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THE RULES GOVERNING COSMETIC PRODUCTS IN THE EUROPEAN UNION

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FOREWORD

In the early 1970's, the Member States of the EU decided to harmonise their national cosmetic regulations in order to enable the free circulation of cosmetic products within the Community. As a result of numerous discussions between experts from all Member States, Council Directive 76/768/EEC was adopted on 27 July 1976. The principles laid down in the Cosmetics Directive take into account the needs of the consumer while encouraging commercial exchange and eliminating barriers to trade. For example, if a product is to move freely within the EU, the same labelling, packaging and safety regulations must apply. This is one of the main objectives of the Cosmetics Directive: to give clear guidance on what requirements a safe cosmetic product should fulfil in order to freely circulate within the EU, without pre-market authorisation. The Cosmetics Directive aims to guarantee the safety of cosmetic products for human use. This safety relates to composition, packaging and information and it falls totally under the responsibility of the producer or the importer into the EU who is responsible for the marketing liability. There is no pre-market control for cosmetic products at Member State or EU level. Control of cosmetic products within the EU is assured through the responsibility of the person who places the product on the market, a simple notification of manufacturing/importing site, and an in-market surveillance system.

Volume 1 is the first part of a series of volumes entitled "The Rules governing cosmetic products in the European Union", published by the Office for Official Publications of the European Communities and listed on the preceding page. Volume 1 includes the legislation applicable to cosmetic products. This legislation consists of the basic Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, and Commission Directive 95/17/EC laying down detailed rules for the application of Council Directve 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products. This legislative framework has been completed by an Inventory and Common Nomenclature of Ingredients employed in cosmetic products established in Commission Decision 96/335/EC of 8 May 1996 which is not incorporated in this Volume.

Council Directive 76/768/EEC has already undergone six amendments and 23 adaptations to technical progress. With a view to facilitating consultation, it is set out here in codified form for internal use by the competent Commission departments. This codified text is available to the public but has no force in law. Where doubts exist, the original texts as published in the Official Journal of the European Communities, should be consulted.

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			Number	Date	
Basic Council Directive	76/768/EEC	27.07.1976	L 262	27.09.1976	Articles 1 to 15 Ann. I: Illustrative list by category of cosmetic products Ann. II: List of forbidden substances Ann. III: List of restricted substances Positive List (PL) for cosmetic colouring agents permitted for all uses Ann. IV: List of restricted substances provisionally allowed List of cosmetic colouring agents provisionally allowed Ann. V: List of substances regulated at national level by EC Member States
1st amendment Council Directive	79/661/EEC	24.07.1979	L 192	31.07.1979	Ann. IV: Provisional authorisations prolonged
1st adapting Commission Directive	82/147/EEC	11.02.1982	L 63	06.03.1982	Ann. II: Ban AETT (362)
2nd amendment Council Directive	82/368/EEC	17.05.1982	L 167	15.06.1982	Articles: — provisional authorisations Ann. IV prolonged — new procedure to adapt Annexes (Art. 8.2) — introduction procedure of Prior National Approval limited to 3 years (Art. 8.a) — Unavoidable traces of banned materials permitted (Art. 4.2) Ann. III: new version Part 1 Ann. III + IV: new version of PL for cosmetic colouring agents Ann. VI: Introduction of PL for preservatives
2nd adapting Commission Directive	83/191/EEC	30.03.1983	L 109	26.04.1983	Ann. II, III, IV, V: — Ba/Sr/Zr lakes — Al/Zr complexes, silver nitrate
3rd adapting Commission Directive	83/341/EEC	29.06.83	L 188	13.07.1983	Ann. II, III, V: Hair Dyes - ban OPD + salts 2,4 DAT + salts; permanent listing PPD + salts
4th adapting Commission Directive	83/496/EEC	22.09.1983	L 275	08.10.1983	Ann. VI: addition 36, 45
3rd amendment Council Directive	83/574/EEC	26.10.1983	L 332	28.11.1983	Articles: new definition of the date of minimum durability, period reduced to 30 months Introduction Ann. VII : PL for UV-Filters
5th adapting Commission Directive	84/415/EEC	18.07.1984	L 228	25.08.1984	Ann. II: ban aristolochic acid Ann. III: hydrogen peroxide, hydroquinone, nicomethanol hydrofluoride, silver nitrate

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6th adapting Commission Directive	85/391/EEC	16.07.1985	L 224	22.08.1985	Ann. II: ban specific hydroquinone ethers Ann. III: selenium disulfide; Al/Zr complexes Ann. VI: labelling formaldehyde
7th adapting Commission Directive	86/179/EEC	28.02.1986	L 138	24.05.1986	Ann. II: ban chloroform, TCDD, dimethoxane, sodium pyrithione Ann. III : DMET, 8-hydroxyquinoline Ann. III+IV: new version of PL for cosmetic colouring agents
8th adapting Commission Directive	86/199/EEC	26.03.1986	L 149	03.06.1986	Ann. IV : introduction of other uses 43 Ann. VI : new version of PL for preservatives
9th adapting Commission Directive	87/137/EEC	02.02.1987	L 56	26.02.1987	Ann. II: ban Captan (370), Hexachlorophene (371), Minoxidil (372) Ann. III : Methanol, 77288 - 77289 Ann. VI: — permanent: 40 — deleted: 9, 12, 13
10th adapting Commission Directive	88/233/EEC	02.03.1988	L 105	26.04.1988	Ann. II: ban tribromsalan, retinoic acid, phytolacca, 2,4-DAA, 2,5-DAA, 12140, 26105, 42555 Ann. III/1: etidronic acid, phenoxypropanol Ann. III/2: delete 13065, add Acid Red 195 Ann. IV/2: delete 12700, 44025, 73312 Ann. VI: — permanent: 41, 42, 43 — deleted: 7, 8, 10, 11, 14, 18, 22, 23, 24
4th amendment Council Directive	88/667/EEC	21.12.1988	L 382	31.12.1988	Articles: — Hair dyes excluded from cosmetic colouring agents list — labelling container + packaging — elimination 6 week deadline in Safeguard Clause (Art. 12) Ann. III becomes only restrictive list Ann. IV becomes only cosmetic colouring agents PL
11th adapting Commission Directive	89/174/EEC	21.02.1989	L 64	08.03.1989	Ann. II: ban Padimate A, benzoyl peroxide, 2A-4NP, 2A-5NP Ann. III/2: add 8-OH-quinoline Ann. IV/2: delete 15800, 19120, 20470, 21115, 42170, 45190, 47000, 73905, 75660 Ann. V: delete oestrogens Ann. VI: — 39 reduce concentration — add 48 (prov.) Ann. VII: new version Part 2
5th amendment Council Directive	89/679/EEC	21.12.1989	L 398	30.12.1989	Articles: — CATP procedure prolonged indefinitely
12th adapting Commission Directive	90/121/EEC	20.02.1990	L 71	17.03.1990	Ann. II: ban steroid antiandrogens, zirconium compounds, thyrothricine, acetonitrile, tetrahydrozoline, 13065, 42535, 42640, 61554, Ann. III: lead acetate Ann. IV: — delete 21110, 42045, 44045 — add Solvent Yellow 98 (prov.) Ann. V: transfers to other Annexes

Existing EEC directive	Reference number	Date of signature	EC Publication O.J. Number	EC Publication O.J. Date	CONTENT (main items)
13th adapting Commission Directive	91/184/EEC	12.03.1991	L 91	12.04.1991	Ann. II: ban 8-OH-quinoline, pyrithione diS, lidocaine, 12075, 45170 Ann. III: add Mg fluoride Ann. IV: 15585 move to Part 2 Ann. V: transfers to other Annexes Ann. VI: add 27 (prov.) Ann. VII: add 7
14th adapting Commission Directive	92/8/EEC	18.02.1992	L 70	17.03.1992	Prolongation of all provisionally listed substances until 30.06.1992
15th adapting Commission Directive	92/86/EEC	21.10.1992	L 325	11.11.1992	Ann. II: — ban 15585, Sr lactate, Sr nitrate, Sr polycarboxylate, Pramocaine, 4-Ethoxy-MPD, 2,4-Diaminophenyl-ethanol, catechol, pyrogallol, nitrosamines, secondary dialkanolamines Ann. III: — add Sr chloride, Sr acetate, talc, nitrosamines precursors — H_2O_2 add oral hygiene Ann. III Part 2 + Ann. IV Part 2: nothing listed anymore Ann. VI — 36 sunscreen use with limit — add 51 , 29 (prov.) Ann. VII: — delete 1, 4, 16
6th amendment Council Directive	93/35/EEC	14.06.1993	L 151	23.06.1993	Articles: — definition modified — overall safety clause modified — ban animal testing foreseen — inventory cosmetic ingredients — off-pack labelling in some cases — labelling of product function — ingredient labelling — claims concerning animal testing — requirements to Poison Centres modified — Product Information required — Notification manufacturing premises — All Annexes via CATP procedure — new Annex VIII
16th adapting Commission Directive	93/47/EEC	22.06.1993	L 203	13.08.1993	Ann. II: — ban 4 A-2NP Ann. III: — warning: gloves for hair dyes + H_2O_2 — add (Part 2) Sr peroxide, phenolphthalein Ann. VII: — move 33 to prov.
17th adapting Commission Directive	94/32/EC	29.06.1994	L 181	15.07.1994	Ann. II: — ban 2-Methyl-MPD Ann. III: — talc lab. baby prod. modified — add SrO_2, $Sr(OH)_2$ Ann. VI: — add formic acid and its sodium salt — 21 reduction conc. + RO only — delete 26, 27, 28 Ann.VII: — add 11 (prov.) — delete 24

■ List of official texts of Directive 76/768/EEC and its official amendments

Existing EEC directive	Reference number	Date of signature	EC Publication O.J.		CONTENT (main items)
			Number	Date	
18th adapting Commission Directive	95/34/EC	10.07.1995	L 167	18.07.1995	Ann.II: — ban furocoumarines — ban musk ambrette — ban benzethonium chloride — ban cells, tissues, products of human origin — ban phenolphthalein Ann.VII/1: — add octocrylene (10)
19th adapting Commission Directive	96/41/EC	25.06.1996	L 198	08.08.1996	Ann. II: — ban urocanic acid (418) Ann. III: — add $Ca(OH)_2$ and LiOH Ann. VI: — Part 1: add 52 Ann. VII: — Part 1: add 11
20th adapting Commission Directive	97/1/EC	10.01.1997	L 16	18.01.1997	Ann. II: — ban bovine, ovine and caprine tissues and fluids from encephalon, spinal cord and eyes, and derivatives
Commission Directive postponing the ban on animal testing	97/18/EC	17.04.1997	L 114	01.05.1997	The ban on animal testing of cosmetic ingredients and their combinations is postponed until 30 June 2000
21st adapting Commission Directive	97/45/EC	14.07.1997	L 196	24.07.1997	Ann. II: — ban crude and refined coal tars Ann. VI/1: — add benzethonium chloride (53) Ann. VII/1: — add octyl methoxycinnamate (12)
22nd adapting Commission Directive	98/16/EC	05.03.1998	L 77	14.03.1998	Ann. II: — amendment of reference number 419 to derogate tallow derivatives
23rd adapting Commission Directive	98/62/EC	03.09.1998	L 253	15.09.1998	Ann. II: — ban of moskene (421) and musk tibetene (422) Ann. VI/1: — add benzalkonium chloride (54) Ann. VII/1: — add 13, 14, 15, 16, 17, 18, 19, 20

COUNCIL DIRECTIVE 76/768/EEC

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

Note: The text of the recitals below only covers the recitals included with the original Directive of 1976 and with the 6th Amendment of 1993.

Recitals of original Directive 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,

Having regard to the opinion of the Economic and Social Committee,

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;

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 products 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,

Recitals of 6th Amendment – Directive 93/35/EEC

Whereas the legal ambiguities in Directive 76/768/EEC particularly in Articles 1 and 2, should be removed;

Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered so that all issues relating to their use and the resulting action at Community level may be assessed with a view, in particular, to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of that data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas that inventory will be indicative and is not intended to constitute a limitative list of substances used in cosmetic products;

Whereas greater transparency is needed regarding the ingredients employed in cosmetics if the latter are to be placed on the market without any prior procedure, if the necessary information on the finished product is to be available solely at the place of manufacture or of initial importation into the Community and if better information is to be provided to the consumer; whereas such transparency should be achieved by indication of a product's function and of the ingredients used in a cosmetic product on its packaging; whereas where for practical reasons it is impossible to indicate the ingredients and any warnings regarding use on the container or the packaging, such particulars should be enclosed so that the consumer may have access to all necessary information;

Whereas, with regard to the finished cosmetic product, it should be made clear which information is to be made available to the monitoring authorities of the place of manufacture or of initial importation into the Community market; whereas that information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product;

Whereas, however, for reasons of monitoring, the competent authority should be apprised of the place of manufacture and of the information needed for rapid and appropriate medical treatment in the event of difficulties;

Whereas the Commission should be authorized to amend Annexes I and VIII to Directive 76/768/EEC in view of their illustrative and technical nature;

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product should take account of the requirements of Directive 86/609/EEC which concerns the protection of animals used for experimental and other scientific purposes, and in particular Article 7 (2) thereof;

Whereas testing on animals of ingredients or combinations of ingredients should be banned as from 1 January 1998; whereas, however, that date should be postponed where alternative methods of testing have not been scientifically validated; whereas the Commission should submit a report on progress made with regard to such methods,

HAS ADOPTED THIS DIRECTIVE:

COSMETICS DIRECTIVE 76/768/EEC

Article 1

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.

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.

Article 2

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.

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.

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;

(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;

(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;

(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 30 June 2000 in order to meet the requirements of this Directive.

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 Cosmetic Products and Non-Food Products intended for Consumers.

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.

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.

Article 5

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 conditions 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 5a

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 Organisation, 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

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:

(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, 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;

(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;

(f) the function of the product, unless it is clear from the presentation of the product;

(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 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.

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.

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.

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. 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.

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*.

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.

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 ([1]).

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

([1]) OJ No L 15, 17.1.1987, p. 29.

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*.

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

Article 8

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 Cosmetic Products and Non-Food Products intended for Consumers, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.

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. The Member State 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 on Cosmetic Products and Non-Food Products intended for Consumers 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

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 62 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 3 months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

Without prejudice to Article 5, and not later than 1 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.

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.

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 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 which 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

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 chemical 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

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. ß-Acetoxyethyl trimethyl ammonium hydroxide (acetylcholine) and its salts
3. Deanol aceglumate*
4. Spironolactone*
5. [4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl] acetic acid and its salts
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. 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. Betoxycaine* and its salts
24. Zoxazolamine*
25. Procainamide*, its salts and derivatives
26. Benzidine
27. Tuaminoheptane*, its isomers and salts

(*) 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.

28. Octodrine* and its salts
29. 2-Amino-1,2-bis (4-methoxyphenyl) ethanol and its salts
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)-7H-furo [3,2-g] chromen-7-one)
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
41. *Apocynum cannabinum L.* and its preparations
42. Apomorphine (5, 6, 6a, 7-tetrahydro-6-methyl-4H-dibenzo [de,g]-quinoline-10,11-dihydric alcohol) and its salts
43. Arsenic and its compounds
44. *Atropa belladona 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, and Annex IV, Part 2.
47. Benzene
48. Benzimidazol-2(3H)-one
49. Benzazepines and benzadiazepines
50. 1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts
51. 2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts
52. Isocarboxazide*
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

(*) 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.

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, *Cantharis vesicatoria*
70. (1R, 2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
71. Phenprobamate*
72. Nitroderivatives of carbazole
73. Carbon disulphide
74. Catalase
75. Cephaeline and its salts
76. *Chenopodium ambrosioides* (essential oil)
77. 2,2,2-Trichloroethane-1,1-diol
78. Chlorine
79. Chlorpropamide*
80. Diphenoxylate* hydrochloride
81. 4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82. Chlorzoxazone*
83. 2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)
84. Chlorprothixene* and its salts
85. Clofenamide*
86. N,N-Bis (2-chloroethyl) methylamine N-oxide and its salts
87. Chlormethine* and its salts
88. Cyclophosphamide* and its salts
89. Mannomustine* and its salts
90. Butanilicaine* and its salts
91. Chlormezanone*
92. Triparanol*
93. 2-[2-(4-Chlorophenyl)-2-phenylacetyl] indan 1,3-dione (chlorophacinone - ISO)

(*) 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.

94. Chlorphenoxamine*
95. Phenaglycodol*
96. Chloroethane
97. Chromium; chromic acid and its salts
98. *Claviceps purpurea Tul.*, its alkaloids and galenical preparations
99. *Conium maculatum L.* (fruit, powder, galenical preparations)
100. Glycyclamide*
101. Cobalt benzenesulphonate
102. Colchicine, its salts and derivatives
103. Colchicoside and its derivatives
104. *Colchicum autumnale L.* and its galenical preparations
105. Convallatoxin
106. *Anamirta cocculus L.* (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-α-Cyclohexylbenzyl (N,N,N',N'-tetraethyl) trimethylenediamine (phenetamine)
113. Cyclomenol* and its salts
114. Sodium hexacyclonate*
115. Hexapropymate*
116. Dextropropoxyphene*
117. O,O'-Diacetyl-N-allyl-N-normorphine
118. Pipazetate* and its salts
119. 5-(α, ß -Dibromophenethyl)-5-methylhydantoin
120. N,N'-Pentamethylenebis (trimethylammonium) salts, e.g. pentamethonium bromide*
121. N,N'-[(Methylimino) diethylene] bis (ethyldimethylammonium) salts, e.g. azamethonium bromide*
122. Cyclarbamate*
123. Clofenotane* (DDT - ISO)
124. Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*
125. Dichloroethanes (ethylene chlorides)
126. Dichloroethylenes (acetylene chlorides)

(*) 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.

127. Lysergide* and its salts
128. 2-Diethylaminoethyl-3-hydroxy-4-phenylbenzoate and its salts
129. Cinchocaine* and its salts
130. 3-Diethylaminopropyl cinnamate
131. O,O'-Diethyl O-4-nitrophenyl phosphorothioate (parathion - ISO)
132. [Oxalylbis(iminoethylene)] bis (O-chlorobenzyl) diethylammonium salts, e.g. ambenomium chloride*
133. Methyprylon* 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. Piprocurarium*
138. Propyphenazone*
139. Tetrabenazine* and its salts
140. Captodiame*
141. Mefeclorazine* and its salts
142. Dimethylamine
143. 1,1-Bis(dimethylaminomethyl)propyl benzoate (amydricaine, alypine) and its salts
144. Methapyrilene* and its salts
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*
157. Benactyzine*
158. Benzatropine* and its salts
159. Cyclizine* and its salts

(*) 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.

160. 5,5-Diphenyl-4-imidazolidone
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 Annex VII, Part 2
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. Metheptazine* and its salts
175. Methylphenidate* and its salts
176. Doxylamine* and its salts
177. Tolboxane*
178. 4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol
179. Parethoxycaine* and its salts
180. Fenozolone*
181. Glutethimide* and its salts
182. Ethylene oxide
183. Bemegride* and its salts
184. Valnoctamide*
185. Haloperidol*
186. Paramethasone*
187. Fluanisone*
188. Trifluperidol*
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
192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*

(*) 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.

193. Galantamine*

194. Progestogens

195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC - ISO)

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)

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-dimethanonaphthalene (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

205. Methocarbamol*

206. Propatylnitrate*

207. 4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin

208. Fenadiazole*

209. Nitroxoline and its salts

210. Hyoscyamine, its salts and derivatives

211. *Hyoscyamus niger L.* (leaves, seeds, powder and galenical preparations)

212. Pemoline* and its salts

213. Iodine

214. Decamethylenebis (trimethylammonium) salts, e.g. decamethonium bromide

215. Ipecacuanha (*Cephaelis ipecacuanha Brot.* and related species) (roots, powder and galenical preparations)

216. (2-Isopropylpent-4-enoyl)urea (apronalide)

217. α-Santonin ((3S, 5aR, 9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto [1,2-b] furan-2,8-dione)

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 Annex VI, Part 1

222. 3,4,5-Trimethoxyphenethylamine and its salts

223. Metaldehyde

(*) 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.

224. 2-(4-Allyl-2-methoxyphenoxy)-N-N-diethylacetamide and its salts
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)
235. Carisoprodol*
236. Meprobamate*
237. Tefazoline* and its salts
238. Arecoline
239. Poldine methylsulfate*
240. Hydroxyzine*
241. 2-Naphthol
242. 1- and 2-Naphthylamines and their salts
243. 3-(1-Naphthyl)-4-hydroxycoumarin
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. Nitrocresols 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

(*) 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.

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. Pentaerithrityl tetranitrate*
266. Petrichloral*
267. Octamylamine* and its salts
268. Picric acid
269. Phenacemide*
270. Difencloxazine*
271. 2-Phenylindane-1,3-dione (phenindione)
272. Ethylphenacemide*
273. Phenprocoumon*
274. Fenyramidol*
275. Triamterene* and its salts
276. Tetraethyl pyrophosphate (TEPP - ISO)
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. α-Piperidin-2-yl-benzyl acetate laevorotatory threoform (levophacetoperane) and its salts
285. Pipradrol* and its salts
286. Azacyclonol* and its salts
287. Bietamiverine*
288. Butopiprine* and its salts
289. Lead and its compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated

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290. Coniine

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

296. Gold salts

297. Selenium and its compounds with the exception of selenium disulphide under the conditions set out under the reference No 49 in Annex III, Part 1

298. *Solanum nigrum L.* and its galenical preparations

299. Sparteine and its salts

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 $-NH_2$ 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

313. Xylometazoline* and its salts

314. Tetrachloroethylene

315. Carbon tetrachloride

316. Hexaethyl tetraphosphate

317. Thallium and its compounds

318. *Thevetia neriifolia Juss.*, glycoside extract

([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).

(*) 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.

319. Ethionamide*

320. Phenothiazine* and its compounds

321. Thiourea and its derivatives, with the exception of the one listed in Annex III, Part 1

322. Mephenesin* 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)

324. Tranylcypromine* 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

334. Vinyl chloride monomer

335. Ergocalciferol* and cholecalciferol (vitamins D2 and D3)

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] ethyldimethylamine maleate

347. Tripelennamine*

348. Tetrachlorosalicylanilides

349. Dichlorosalicylanilides

350. Tetrabromosalicylanilides

351. Dibromosalicylanilides

(*) 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.

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. 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.

359. Oil from the seeds of *Laurus nobilis 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.

361. 5,5' -Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypoiodite

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-tetrahydro-naphthalene (acetyl ethyl tetramethyl tetralin, AETT)

363. o-Phenylenediamine and its salts

364. 4-Methyl-m-phenylenediamine and its salts

365. Aristolochic acid and its salts

366. Chloroform

367. 2,3,7,8,-Tetrachlorodibenzo-p-dioxin

368. 2,6-Dimethyl-1,3-dioxan-4-yl acetate (dimethoxane)

369. Pyrithione sodium (INNM)

370. N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)

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. 3,4',5-Tribromosalicylanilide (Tribromsalan)

374. *Phytolacca Spp.* and their preparations

375. Tretinoin* (retinoic acid and its salts)

376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole – CI 76050) and their salts

377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and their salts

378. Colouring agent CI 12140

(*) 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.

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))

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

386. Colouring agent CI 42640

387. Colouring agent CI 13065

388. Colouring agent CI 42535

389. Colouring agent CI 61554

390. Antiandrogens with steroid structure

391. Zirconium and its compounds, with the exception of the complexes under reference No 50 in Annex III, Part 1 and of zirconium lakes, salts and pigments of colouring agents listed with reference No 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

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

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

413. 2-Methyl-m-phenylenediamine

414. 4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)

416. Cells, tissues or products of human origin

417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein *)

418. 3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)

419. (a) the skull, including the brain and eyes, tonsils and spinal cord of:

— bovine animals aged 12 months

— ovine and caprine animals which are aged over 12 months or have a permanent incissor tooth erupted through the gum;

(b) the spleens of ovine and caprine animals and ingredients derived therefrom.

However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:

— transesterification or hydrolysis at at least: 200 °C, 40 bars (40,000 hPa) for 20 minutes (glycerol and fatty acids and esters),

— saponification with NaOH 12M (glycerol and soap):

— batch process: at 95 °C for 3 hours

or

— continuous process: at 140 °C, 2 bars (2 000 hPa) for 8 minutes or equivalent conditions.

420. Crude and refined coal tars

421. 1,1,3,3,5,-Pentamethyl-4,6-dinitroindane (moskene)

422. 5-tert-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene)

(*) 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.

ANNEX III – PART 1

List of substances which cosmetic products must not contain except subject to 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 authorised 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	Thioglycolic 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 7 to 9.5 The abovementioned percentages are calculated as thioglycolic 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

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
2b	Thioglycolic 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 thioglycolic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — May cause sensitisation 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 %		
7	Dichloromethane		35 % (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 %)	0.2 % as maximum impurity content	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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 — Contains phenylenediamines — Do not use to dye eyelashes or eyebrows (b) — For professional use only — Contains phenylenediamines — Can cause an allergic reaction — Wear suitable gloves
9	Methylphenylene-diamines, 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 — Contains phenylenediamines — Do not use to dye eyelashes or eyebrows (b) — For professional use only — Contains phenylene-diamines — Can cause an allergic reaction — Wear suitable gloves

([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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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 an allergic reaction — Wear suitable gloves
11	Dichlorophen (*)		0.5 %		— Contains dichlorophen
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 % H_2O_2 (40 volumes) present or released 4 % of H_2O_2 present or released 2 % of H_2O_2 present or released 0.1 % of H_2O_2 present or released		(a) (b) (c) — Contains hydrogen peroxide — Avoid contact with eyes — Rinse eyes immediately if product comes into contact with them (a) — Wear suitable gloves

(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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil Contains formaldehyde (2)
14	Hydroquinone (1)	(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 — Avoid contact with the eyes — Apply to small areas — If irritation develops discontinue use — Do not use on children under the age of 12

(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 the value given in column d.

(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 authorised 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	(a) 5 % by weight ([1])		(a) — Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
		(b) Hair straightener	(b)		(b)
		1. general use	1. 2 % by weight ([1])		1. — Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
		2. professional use	2. 4.5 % by weight ([1])		2. — For professional use only — Avoid contact with eyes — Can cause blindness
		(c) pH adjuster - depilatories	(c) up to pH 12.7		(c) — Keep out of reach of children — Avoid contact with eyes
		(d) Other uses as pH adjuster	(d) up to pH 11		
15b	Lithium hydroxide	(a) Hair straightener	(a)		(a)
		1. general use	1. 2 % by weight ([1])		1. — Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
		2. professional use	2. 4.5 % by weight ([1])		2. — For professional use only — Avoid contact with eyes — Can cause blindness
		(b) Other uses			

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

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) Other uses	(a) 7 % by weight calcium hydroxide		— Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
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
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5 % calculated as quinine base (b) 0.2 % calculated as quinine base		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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
		2. professional use			2. — For professional use only — Contains resorcinol — Rinse eyes immediately if product comes into contact with them
		(b) Hair lotions and shampoos	(b) 0.5 %		(b) — Contains Resorcinol
23	(a) Alkali sulphides	a) Depilatories	a) 2 % calculated as sulphur pH ≤ 12.7		(a) — Keep out of reach of children — Avoid contact with eyes
	(b) Alkaline earth sulphides	(b) Depilatories	(b) 6 % calculated as sulphur pH ≤ 12.7		(b) — Keep out of reach of children — Avoid contact with the eyes

(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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
24	Water-soluble zinc salts with the exception of zinc-4-hydroxybenzene-sulphonate 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 monofluoro-phosphate	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 monofluoro-phosphate	Ditto	0.15 % Ditto		— Contains sodium monofluorophosphate
28	Potassium monofluoro-phosphate	Ditto	0.15 % Ditto		— Contains potassium monofluorophospate
29	Calcium monofluoro-phosphate	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

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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
36	Hexadecyl ammonium fluoride	Ditto	0.15 % Ditto		— Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2-hydroxyethyl-ammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride	Ditto	0.15 % Ditto		— Contains 3-(N-Hexadecyl-N-2-hydroxyethyl-ammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride
38	N,N',N'-Tris(polyoxyethylene)-N-hexadecyl-propylenediamine 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

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
42	Ammonium fluorosilicate	Ditto	0.15 % Ditto		— Contains ammonium fluorosilicate
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 aerosols 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
49	Selenium disulphide	Anti-dandruff shampoos	1 %		— Contains selenium disulphide — Avoid contact with eyes or damaged skin

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
50	Aluminium zirconium chloridehydroxide complexes $Al_xZr(OH)_yCl_z$ and the aluminium zirconium chloridehydroxide glycine complexes	Anti-perspirants	20 % as anhydrous aluminium zirconium chloridehydroxide 5.4 % as zirconium	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 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
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 iso-propyl alcohol	5 % calculated as a % of ethanol and isopropyl alcohol		
53	Etidronic acid and its salts (1-hydroxy-ethylidene-diphosphonic acid and its salts)	(a) Hair-care (b) Soap	1.5 % expressed as etidronic acid 0.2 % expressed as etidronic acid		
54	1-Phenoxypropan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %	As a preservative, see Annex VI, Part 1, No 43	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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	3.5 % calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 3.5 %		— Contains strontium chloride. — Frequent use by children is not advisable
		(b) Shampoo and face care products	2.1 % calculated as strontium When mixed with other permitted strontium compounds the total strontium content must not exceed 2.1 %		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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 by children under three years of age (b) Other products			(a) — Keep powder away from children's nose and mouth
60	Fatty acid dialkanolamides		Maximum dialkanolamine content: 0.5 %	— 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	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
61	Monoalkanolamines		Maximum dialkanolamine content: 0.5 %	— Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0.5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers	
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2.5 %	(a) (b): — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0.5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
63	Strontium hydroxide	pH-regulator in depilatory products	3.5 % calculated as strontium, max. pH of 12.7		— 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	— Avoid contact with eyes — Rinse eyes immediately if product comes into contact with them — For professional use only — Wear suitable gloves

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

Note: no substance is listed in this section for the present time.

ANNEX IV – 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		
12085 ([3])	Red	X				3 % max. 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
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122

([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.

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
14815	Red	X				E 125
15510 (3)	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 (3)	Red	X				3 % max. concentration in the finished product
15800	Red			X		
15850 (3)	Red	X				
15865 (3)	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				
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'-dimethyl-benzidine concentration in the colouring agent: 5 ppm
20170	Orange			X		
20470	Black				X	
21100	Yellow				X	Maximum 3,3'-dimethyl-benzidine 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 %

(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.

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
27290 (3)	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		
42051 (3)	Blue	X				E 131
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	5 ppm max. concentration in the finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				E 142
45100	Red				X	
45190	Violet				X	
45220	Red				X	
45350	Yellow	X				6 % max. 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
45410 (3)	Red	X				Ditto

(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.

Colour Index Number or Denomination	Colour	Field of application				Other limitationsand requirements (2)
		1	2	3	4	
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		
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	
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	
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				

(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.

Colour Index Number or Denomination	Colour	Field of application				Other limitationsand requirements (2)
		1	2	3	4	
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
77289	Green	X				Free from chromate ion
77346	Green	X				
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
Beetroot red	Red	X				E 162
Anthocyanins	Red	X				E 163
Aluminium, zinc, magnesium and calcium stearates	White	X				
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	
Acid Red 195	Red			X		

(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.

ANNEX IV – 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 eyes, in particular eye make-up and eye make-up remover.

Column 3: Colouring agents allowed in all 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		

Note: no colorant is listed in this section for the present time.

([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.

ANNEX V

List of substances excluded from the scope of the Directive

5. Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed 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.

ANNEX VI

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%.

ANNEX VI – PART 1

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 3 years of age, except for shampoos	— Not to be used for children under 3 years of age (1)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (+)	0.6 % (acid)		
5	Formaldehyde and 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 phenol		
8	Pyrithione zinc (INN) (+)	0.5 %	Authorized in products rinsed off, forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogensulphites (+)	0.2 % expressed as free SO_2		

(1) Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

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
10	Sodium iodate	0.1 %	Rinse-off products only	
11	Chlorobutanol (INN)	0.5 %	Prohibited in aerosol dispensers (sprays)	— Contains chlorobutanol
12	4-Hydroxybenzoic acid 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 (Dehydroacetic 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'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1 %		
16	Thiomersal (INN)	0.00 7% (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	

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
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'-Tetra-chloroazobenzene less than 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene less than 1 ppm	
24	4-Chloro-m-cresol (+)	0.2 %	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan (INN) (+)	0.3 %		
26	4-Chloro-3,5-xylenol (+)	0.5 %		
27	3,3'-Bis(1-hydroxymethyl-2,5-dioxoimidazolidin-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 %		

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
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 % 0.5 %	Products rinsed-off For other products	
36	1,2-Dibromo-2,4-dicyanobutane	0.1 %	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025 %	
37	6,6-Dibromo-4,4-dichloro-2,2'-methylenediphenol (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 (Chlorophene)	0.2 %		

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
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	
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-imidazolinidyl-4)-N'-(hydroxymethyl)urea	0.5 %		
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy-benzoate) (+)	0.1 %		
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-dioxa-1-azabicyclo [3.3.0] octane	0.3 %	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	

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
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		Avoid contact with the eyes

ANNEX VI – 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	c	d	e	f
21	Benzylhemiformal	0.03 %	For rinse-off products only		30.06.1999
29	3-Iodo-2-propynyl butylcarbamate (iodopropynyl butylcarbamate)	0.05 %	Not for oral hygiene and lip products		30.06.1999

ANNEX VII

List of UV filters which cosmetic products may contain

For the purpose of this Directive, UV filters are substances which, contained in cosmetic sunscreen 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.

ANNEX VII — PART 1

List of permitted UV filters which cosmetic products may contain

Reference number	Substance	Maximum authorised 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-ylidenemethyl) 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-oxo-bicyclo-(2,2,1) hept-1-ylmethanesulphonic 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 %		
13	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA)	10 %		

([1]) Not required if concentration is 0.5 % or less and when it is used only for product protection purposes.

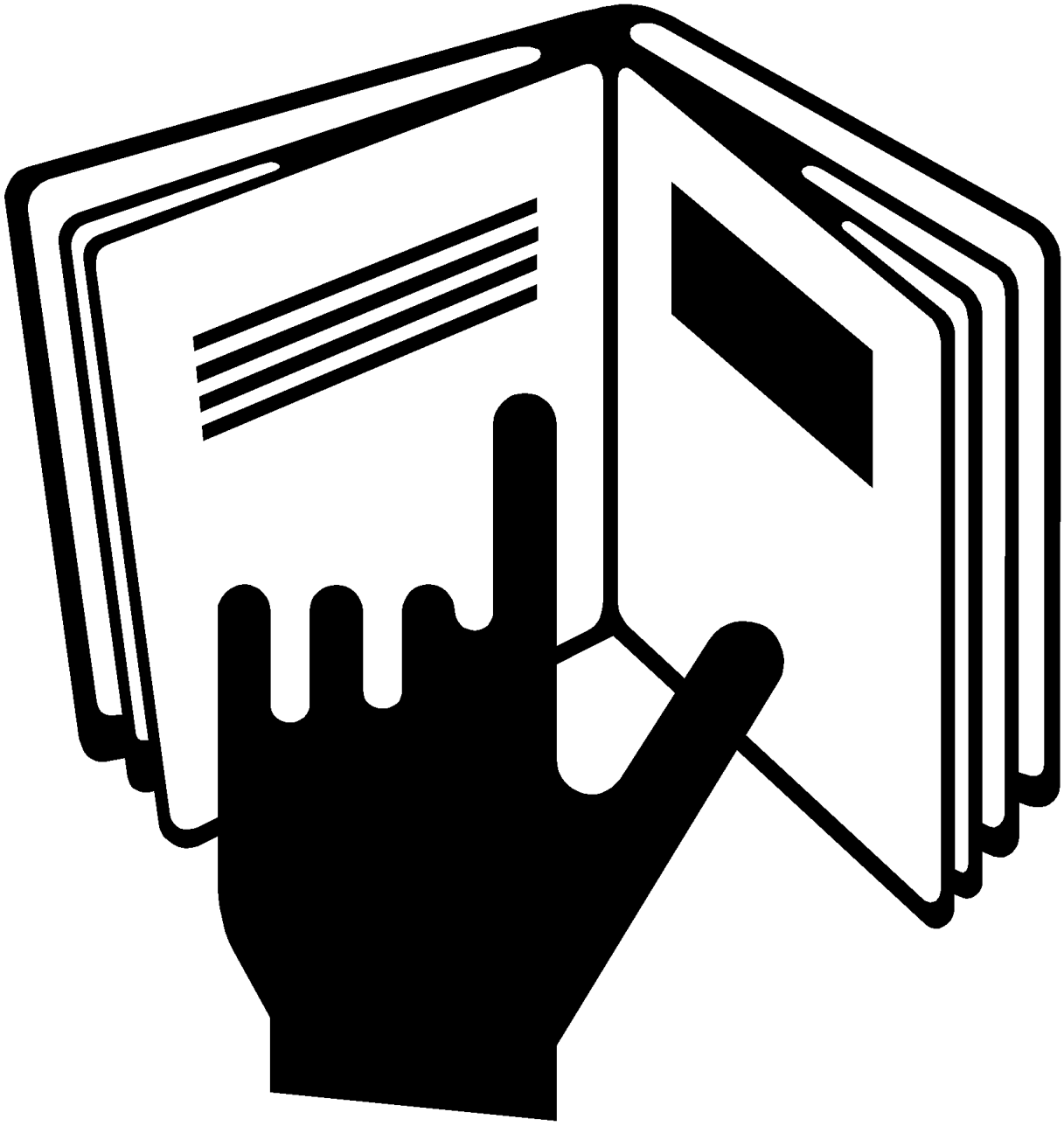
Reference number	Substance	Maximum authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
14	Isopentyl-4-methoxycinnamate (Isoamyl p-Methoxycinnamate)	10 %		
15	2,4,6-Trianilino-(p-Carbo-2'-Ethylhexyl-1'Oxy)-1,3,5-Triazine (Otctyl Triazone)	5 %		
16	Phenol, 2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetramethyl-1-(Trimethylsilyl)Oxy)-Disiloxanyl)Propyl (Drometrizole Trisiloxane)	15 %		
17	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl)aminocarbonyl)phenylamino) 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 %		

ANNEX VII — PART 2

List of permitted UV filters which cosmetic products may provisionally contain

Reference number	Substance	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
5	2-Ethylhexyl-4-dimethyl-aminobenzoate	8 %			30.06.1999
17	2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)	5 % (expressed as acid)			30.06.1999
29	4-Isopropylbenzyl salicyclate	4 %			30.06.1999

ANNEX VIII



COMMISSION DIRECTIVE 95/17/EC

Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ([1]), as last amended by Commission Directive 94/32/EC ([2]), and in particular Article (6) (1) (g) thereof,

Whereas there is a need to specify the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the minimum list of ingredients which must be included on the packaging of cosmetic products, or, where this is impossible for practical reasons, on an enclosed leaflet, label, tape or card;

Whereas approval of confidentiality should not, however, impinge on the other obligations pursuant to Directive 76/768/EEC and the responsibilities arising from the Articles concerning the cosmetic product's safety, from the Annexes, and from the provisions as to the information necessary for appropriate medical treatment and the case-file to which the national monitoring authorities must have access;

Whereas approval of confidentiality should not be prejudicial to consumer safety;

Whereas the request for confidentiality must be submitted in the Member State of manufacture or initial importation into the Community market, which must also have access to the information referred to in Article 7a of Directive 76/768/EEC, as amended by Directive 93/35/EEC ([3]), for control purposes;

Whereas to be adequately assessed and monitored the request must include all the particulars necessary for identifying the applicants, for the identification and human health assessment of the ingredient as used in the cosmetic product(s) and for determining the intended use of the ingredient concerned, as well as the grounds for confidentiality and the name(s) of the product containing the ingredient;

Whereas for economic reasons and in deference to his rights the competent authority should inform the applicant, within a brief period of not more than four months, other than in exceptional cases, of the ruling in this case; whereas any refusal to grant confidentiality should be duly reasoned and the means of appeal and time limits clearly indicated;

Whereas in the interests of transparency and monitoring, the competent authority should allocate a registration number to each request it approves; whereas this number should replace the ingredient in the list of ingredients referred to in Article 6 (1) (g) of Directive 76/768/EEC;

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

([2]) OJ No L 181, 15. 7. 1994, p. 31.

([3]) OJ No L 151, 23. 6. 1993, p. 32.

Whereas all amendments to the particulars contained in the initial request must be communicated by the applicant to the competent authority, which may then withdraw its approval of confidentiality in view of those modifications, or if new information makes such a measure necessary for compelling public health reasons;

Whereas the duration of the right to confidentiality should not exceed five years, subject to the option, in exceptional circumstances, of an extension for a further three years at the most;

Whereas, in the interests of monitoring product safety and proper enforcement of the Directive, the Commission and the other Member States should be adequately informed of the decisions taken by the competent authority; whereas, on the other hand, such decisions should be recognized throughout the Community territory, except for exceptional reasons;

Whereas the measures provided for in this Directive are in accordadnce with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetics Products Sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive shall apply without prejudice to the other obligations arising from Directive 76/768/EEC and the responsibilities arising therefrom, in particular from Articles 2, 4, 5, 7 (3) and 7a thereof.

Article 2

Any manufacturer or his agent or person on whose account a cosmetic product is manufactured, or any person responsible for placing an imported cosmetic product on the Community market, who, for reasons of trade secrecy, wishes not to include one or more ingredients of a cosmetic product on the list referred to in Article 6 (1) (g) of Directive 76/768/EEC, shall submit a request to that effect to the competent authority referred to in Article 10 of this Directive of the Member State of the place of manufacture or initial importation, prior to placing the product on the Community market.

Article 3

The request referred to in Article 2 must include the following particulars:

(a) name or style and address or head office of the applicant;

(b) precise identification of the ingredient for which confidentiality is requested, namely:

— the CAS, EINECS and colour index numbers, the chemical name, the IUPAC name, the INCI ([1]) name, the European Pharmacopoiea name, the international non-proprietary name recommended by the World Health Organisation, and the common nomenclature name referred to in Article 7 (2) of Directive 76/768/EEC, where they exist,

— the ELINCS name and the official number allocated to it if it has been notified pursuant to Council Directive 67/548/EEC ([2]) and indication of approval or refusal to approve a request for confidentiality pursuant to Article 19 of that Directive,

([1]) Formerly: CTFA name.

([2]) OJ No L 196, 16. 8. 1967, p. 1.

— where the names or numbers referred to in the first and second indents do not exist, as in the case of certain ingredients of natural origin, the name of the base material, the name of the part of the plant or animal used, and the names of the ingredient's components, such as solvents;

(c) the evaluation of the safety for human health of the ingredient as used in the finished product(s), taking into account the ingredient's toxicological profile, chemical structure and the level of exposure, as specified in Article 7a (1) (d) and (e) and Article 7a (2) of Directive 76/768/EEC;

(d) the envisaged use of the ingredient and in particular the different categories of products in which it will be used;

(e) a detailed justification of why, by way of exception, confidentiality is sought; for example:

— the fact that the identity of the ingredient or its function in the cosmetic product to be marketed has not been described in the literature and is unknown to others in the trade,

— the fact that the information is not yet in the public domain, even though a patent application has been lodged for the ingredient or its use,

— the fact that if the information were known it would be easily reproducible, to the detriment of the applicant;

(f) if known, the name of each product which is to contain the ingredient(s), and if different names are to be used in the Community market, precise details on each one of them.

If the name of a product is not yet known, it may be communicated at a later date, but at least 15 days before placing the product on the market.

If the ingredient is used in several products, one request shall suffice, provided that the products are clearly indicated to the competent authority;

(g) a statement setting out whether a request has been submitted to the competent authority of any other Member State in respect of the ingredient for which confidentiality is sought, and particulars on the outcome of any such request.

Article 4

1. After receipt of the request for confidentiality in accordance with Article 3 the competent authority shall, within a period not exceeding four months, examine the request and inform the applicant in writing of its decision. In the event of approval, the authority shall also communicate the registration number it has allocated to the product in accordance with the procedure laid down in the Annex. However, if there are exceptional reasons, the competent authority may inform the applicant in writing that an additional period of two months will be required for the examination of the request.

2. Any refusal to grant a request for confidentiality must include a statement of reasons; appeal procedures, together with their time limits, must be clearly explained to the applicant.

Article 5

The registration number referred to in Article 4 (1) shall replace the ingredient in question in the list referred to in Article 6 (1) (g) of Directive 76/768/EEC.

Article 6

1. All amendments to the information provided pursuant to Article 3 must be communicated as rapidly as possible to the competent authority that has granted the request for confidentiality. All changes to the names of cosmetic products containing the ingredient must be communicated to the competent authority at least 15 days before those products are placed on the market under their new name.

2. Taking into consideration the amendments referred to in paragraph 1, or if new information makes it imperative to do so, particularly for compelling reasons of public health, the competent authority may withdraw its approval. In this event it shall inform the applicant of its new decision within the time limits and in accordance with the procedure referred to in Article 4.

Article 7

The decision granting the right to confidentiality shall be valid for a period of five years.

If the beneficiary of this decision considers that there are exceptional reasons justifying an extension of this period, he may submit a reasoned request to the competent authority which initially granted the request for confidentiality.

The competent authority shall decide on this new request within this time limits and under the conditions referred to in Article 4.

The confidentiality period shall not be extended by more than three years.

Article 8

1. Member States shall inform the Commission and the other Member States of their decisions to grant requests for confidentiality or to extend such approval, indicating the name or style and address or head office of the applicants, the names of the cosmetic products containing the ingredient in respect of which the request for confidentiality has been granted, and the registration number referred to in Article 4 (1).

The Commission and the other Member States may obtain, on request, a copy of the case file containing the request for confidentiality together with the decision of the competent authority. Particularly in this framework the competent authorities of the Member States and the Commission shall make arrangements to ensure proper cooperation.

2. Member States shall inform the Commission and the other Member States of their reasoned decisions to refuse or to withdraw approval of confidentiality or to refuse to extend the confidentiality period.

3. Member States and the Commission shall take the necessary measures to ensure that confidential data made known to them is not improperly disclosed.

Article 9

Member States shall recognise the decisions taken by a competent authority as to the approval of confidentiality or extension of the confidentiality period.

However, if, after having been informed or after having received a copy of the case file in accordance with the procedure under Article 8 (1), a Member State challenges a decision taken by the competent authority of another Member State, it may ask the Commission to take a decision pursuant to the procedure referred to in Article 10 of Directive 76/768/EEC.

Article 10

Member States shall designate the competent authorities referred to in this Directive and shall inform the Commission thereof, which shall publish them in the *Official Journal of the European Communities*. A Member State may also designate the competent authority of another Member State, willing to accept for the purposes of examination in exceptional cases the requests referred to in Article 2.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 November 1995. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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

Article 12

This Directive shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 19 June 1995.

For the Commission

Emma BONINO

Member of the Commission

ANNEX

Procedure for granting the registration number referred to in Article 4

1. The registration number referred to in Article 4 consists of seven digits, the first two corresponding to the year of approval of confidentiality, the second two to the code assigned to each Member State pursuant to point 2, and the three final digits being assigned by the competent authority.

2. The following codes are allocated to the Member States:

   01 France

   02 Belgium

   03 Netherlands

   04 Germany

   05 Italy

   06 United Kingdom

   07 Ireland

   08 Denmark

   09 Luxembourg

   10 Greece

   11 Spain

   12 Portugal

   13 Finland

   14 Austria

   15 Sweden