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► **B****COUNCIL DIRECTIVE**

of 27 July 1976

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

(76/768/EEC)

(OJ L 262, 27.9.1976, p. 169)

Amended by:

	Official Journal		
	No	page	date
► M1 Council Directive 79/661/EEC of 24 July 1979	L 192	35	31.7.1979
► M2 Commission Directive 82/147/EEC of 11 February 1982	L 63	26	6.3.1982
► M3 Council Directive 82/368/EEC of 17 May 1982	L 167	1	15.6.1982
► M4 Commission Directive 83/191/EEC of 30 March 1983	L 109	25	26.4.1983
► M5 Commission Directive 83/341/EEC of 29 June 1983	L 188	15	13.7.1983
► M6 Commission Directive 83/496/EEC of 22 September 1983	L 275	20	8.10.1983
► M7 Council Directive 83/574/EEC of 26 October 1983	L 332	38	28.11.1983
► M8 Commission Directive 84/415/EEC of 18 July 1984	L 228	31	25.8.1984
► M9 Commission Directive 85/391/EEC of 16 July 1985	L 224	40	22.8.1985
► M10 Commission Directive 86/179/EEC of 28 February 1986	L 138	40	24.5.1986
► M11 Commission Directive 86/199/EEC of 26 March 1986	L 149	38	3.6.1986
► M12 Commission Directive 87/137/EEC of 2 February 1987	L 56	20	26.2.1987
► M13 Commission Directive 88/233/EEC of 2 March 1988	L 105	11	26.4.1988
► M14 Council Directive 88/667/EEC of 21 December 1988	L 382	46	31.12.1988
► M15 Commission Directive 89/174/EEC of 21 February 1989	L 64	10	8.3.1989
► M16 Council Directive 89/679/EEC of 21 December 1989	L 398	25	30.12.1989
► M17 Commission Directive 90/121/EEC of 20 February 1990	L 71	40	17.3.1990
► M18 Commission Directive 91/184/EEC of 12 March 1991	L 91	59	12.4.1991
► M19 Commission Directive 92/8/EEC of 18 February 1992	L 70	23	17.3.1992
► M20 Commission Directive 92/86/EEC of 21 October 1992	L 325	18	11.11.1992
► M21 Council Directive 93/35/EEC of 14 June 1993	L 151	32	23.6.1993
► M22 Commission Directive 93/47/EEC of 22 June 1993	L 203	24	13.8.1993
► M23 Commission Directive 94/32/EC of 29 June 1994	L 181	31	15.7.1994
► M24 Commission Directive 95/34/EC of 10 July 1995	L 167	19	18.7.1995
► M25 Commission Directive 96/41/EC of 25 June 1996	L 198	36	8.8.1996
► M26 Commission Directive 97/1/EC of 10 January 1997	L 16	85	18.1.1997
► M27 Commission Directive 97/18/EC of 17 April 1997	L 114	43	1.5.1997
► M28 Commission Directive 97/45/EC of 14 July 1997	L 196	77	24.7.1997
► M29 Commission Directive 98/16/EC of 5 March 1998	L 77	44	14.3.1998

▶ M30	Commission Directive 98/62/EC of 3 September 1998	L 253	20	15.9.1998
▶ M31	Commission Directive 2000/6/EC of 29 February 2000	L 56	42	1.3.2000
▶ M32	Commission Directive 2000/11/EC of 10 March 2000	L 65	22	14.3.2000
▶ M33	Commission Directive 2000/41/EC of 19 June 2000	L 145	25	20.6.2000
▶ M34	Commission Directive 2002/34/EC of 15 April 2002	L 102	19	18.4.2002
▶ M35	Commission Directive 2003/1/EC of 6 January 2003	L 5	14	10.1.2003
▶ M36	Commission Directive 2003/16/EC of 19 February 2003	L 46	24	20.2.2003
▶ M37	Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003	L 66	26	11.3.2003

Amended by:

▶ A1	Act of Accession of Greece	L 291	17	19.11.1979
▶ A2	Act of Accession of Spain and Portugal	L 302	23	15.11.1985

Corrected by:

▶ C1	Corrigendum, OJ L 255, 25.9.1984, p. 28 (84/415/EEC)
▶ C2	Corrigendum, OJ L 157, 24.6.1988, p. 38 (88/233/EEC)
▶ C3	Corrigendum, OJ L 199, 13.7.1989, p. 23 (89/174/EEC)
▶ C4	Corrigendum, OJ L 273, 25.10.1994, p. 38 (94/32/EC)
▶ C5	Corrigendum, OJ L 341, 17.12.2002, p. 71 (2002/34/EC)
▶ C6	Corrigendum, OJ L 151, 19.6.2003, p. 44 (2002/34/EC)

**COUNCIL DIRECTIVE****of 27 July 1976****on the approximation of the laws of the Member States relating to
cosmetic products****(76/768/EEC)**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

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

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

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

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

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

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

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

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

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

Whereas, in particular, the determination of the methods of analysis together with possible modifications or additions which may have to be made to them on the basis of the results of scientific and technical research, are implementing measures of a technical nature; whereas it

⁽¹⁾ OJ No C 40, 8. 4. 1974, p. 71.

⁽²⁾ OJ No C 60, 26. 7. 1973, p. 16.

▼B

is advisable to entrust their adoption to the Commission, subject to certain conditions specified in this Directive, for the purpose of simplifying and accelerating the procedure;

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

▼M21

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.

▼B

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

▼M14

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.

▼M21

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.

▼B

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.

▼ M3*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;

▼ M14

- (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;

▼ M3

- (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;

▼ M7

- (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.

▼ M37▼ M3

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.

▼ M37*Article 4a*

1. Without prejudice to the general obligations deriving from Article 2, Member States shall prohibit:

- (a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;
- (b) the marketing of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Directive, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;
- (c) the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;
- (d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in Annex V to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and

▼ **M37**

labelling of dangerous substances ⁽¹⁾ or in Annex IX to this Directive.

No later than 11 September 2004 the Commission shall, in accordance with the procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) establish the contents of Annex IX.

2. The Commission, after consultation of the SCCNFP and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, shall establish timetables for the implementation of the provisions under paragraph 1(a), (b) and (d), including deadlines for the phasing-out of the various tests. The timetables shall be made available to the public not later than 11 September 2004 and be sent to the European Parliament and the Council. The period for implementation shall be limited to a maximum of six years after the entry into force of Directive 2003/15/EC in relation to paragraph 1(a), (b) and (d).

(2.1) In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to a maximum of 10 years after the entry into force of Directive 2003/15/EC.

(2.2) The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies should form part of the yearly reports presented pursuant to Article 9.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 may be adapted within a maximum time limit of six years as referred to in paragraph 2 or 10 years as referred to in paragraph 2.1 and after consultation of the entities referred to in paragraph 2.

(2.3) The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies should form part of the yearly reports presented pursuant to Article 9. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in paragraph 2.1, that for technical reasons one or more tests referred to in paragraph 2.1 will not be developed and validated before the expiry of the period referred to in paragraph 2.1 it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

(2.4) In exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consultation of the SCCNFP and by means of a reasoned decision, authorise the derogation in accordance with the procedure referred to in Article 10(2). This authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall only be granted if:

- (a) the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function;
- (b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research Protocol proposed as the basis for the evaluation.

⁽¹⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

▼M37

The decision on the authorisation, the conditions associated with it and the final result achieved shall be part of the annual report to be presented by the Commission in accordance with Article 9.

3. For the purposes of this Article:

- (a) 'finished cosmetic product' means the cosmetic product in its final formulation, as placed on the market and made available to the final consumer, or its prototype.
- (b) 'prototype' means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed.

Article 4b

The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

▼M14*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 condition laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product;
- (d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

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

- definitively allowed, or
- definitively prohibited (Annex II), or
- maintained for a given period specified in Part 2 of Annexes III, IV, VI and VII, or
- deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.

▼M21*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.

▼ M21

2. The inventory shall contain information on:
- the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organization, the EINECS, IUPAC, CAS and colour index numbers, and the common name referred to in Article 7 (2),
 - the usual function(s) of the ingredient in the final product,
 - where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.
3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.

▼ M14*Article 6***▼ M21**

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:

▼ M14

- (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;

▼ M37

- (c) 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 it appears on the packaging.

The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol given in Annex VIIIa followed by the period (in months and/or years);

▼ M21

- (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

▼ M21

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;

▼ M14

- (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;

▼ M21

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

▼ M37

- (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 'aroma'. However, the presence of substances, the mention of which is required under the column 'other limitations and requirements' in Annex III, shall be indicated in the list irrespective of their function in the product.

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 words 'may contain' or the symbol '+/-' 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 referred to in Article 10(2), the Commission may adapt the criteria and conditions set out in 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 ⁽¹⁾ under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.

▼ M21

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

⁽¹⁾ OJ L 140, 23.6.1995, p. 26.

▼ **M21**

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.

▼ **M14**

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. ► **M37** ————— ◀

▼ **M37**

Furthermore, the manufacturer or the person responsible for placing the product on the Community market may take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products. Guidelines shall be adopted in accordance with the procedure referred to in Article 10(2) and published in the *Official Journal of the European Union*. The European Parliament shall receive copies of the draft measures submitted to the Committee.

▼ **B***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.

▼ **M21**

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;

▼ M21

- (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;

▼ M37

- (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 ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There shall be *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

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 available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible;

▼ M21

- (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;

▼ M37

- (h) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of non-member countries.

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.

▼ M21

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⁾.

⁽¹⁾ OJ No L 15, 17. 1. 1987, p. 29.

▼ M21

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

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

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

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

▼ M3*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.

▼ M21

2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the ► **M37** Scientific Committee for 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.

▼ M3*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 States shall forward to the Commission and to the other Member States the text of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the

▼ **M3**

► **M37** Scientific Committee for 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.

▼ **M37***Article 9*

Every year the Commission shall present a report to the European Parliament and the Council on:

- (a) progress made in the development, validation and legal acceptance of alternative methods. The 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 Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁽¹⁾. The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;
- (b) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by non-member countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries;
- (c) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Article 10

1. The Commission shall be assisted by the Standing Committee on Cosmetic Products.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

▼ **B***Article 11*

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

Article 12

1. If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other

⁽¹⁾ OJ L 358, 18.12.1986, p. 1.

▼B

Member States and the Commission thereof, stating the grounds for its decision.

▼M14

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.

▼B

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 of the time limits allowed for the exercise of such remedies.

Article 14

1. Member States shall bring into force the provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

2. Member States may, however, for a period of 36 months from notification of this Directive, authorize the marketing in their territory of cosmetic products which do not conform to the requirements of the Directive.

3. Member States shall ensure that the texts of such provisions of national law as they adopt in the field governed by this Directive are communicated to the Commission.

Article 15

This Directive is addressed to the Member States.

▼B*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 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.

▼B

ANNEX II

▼M3LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE
COMPOSITION OF COSMETIC PRODUCTS▼B

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. ►M3 2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts ◀
3. Deanol aceglumate*
4. Spironolactone*
5. ►M3 [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. Betoxycaïne* and its salts
24. Zoxazolamine*
25. Procainamide*, its salts and derivatives
26. Benzidine
27. Tuaminoheptane*, its isomers and salts
28. Octodrine* and its salts
29. ►M3 2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts ◀
30. 1,3-dimethylpentylamine and its salts
31. 4-Aminosalicic 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. ►M3 Imperatorin (9-(3-methoxybut-2-enyloxy)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 ►M17 ————— ◀

(*) 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.

▼ **B**

40. Antimony and its compounds
41. *Apocynum cannabinum L.* and its preparations
42. ► **M3** Apomorphine (R 5,6,6a, 7-tetrahydro-6-methyl-4*H*-dibenzo [de,g]quinoline-10,11-diol) and its salts ◀
43. Arsenic and its compounds
44. *Atropa belladonna L.* and its preparations
45. Atropine, its salts and derivatives

▼ **M4**

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 (°) in Annex III, Part 2 and Annex IV, Part 2.

▼ **B**

47. Benzene
48. ► **M3** Benzimidazol-2(3*H*)-one ◀
49. ► **M3** Benzazepines and benzodiazepines ◀
50. ► **M3** 1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts ◀
51. ► **M3** 2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts ◀
52. ► **M3** Isocarboxazid* ◀
53. Bendroflumethiazide* and its derivatives
54. Beryllium and its compounds
55. Bromine, elemental
56. Bretylium tosilate*
57. Carbromal*
58. Bromisoval*
59. Brompheniramine* and its salts
60. Benzilium 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. (1*R*,2*S*)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
71. Phenprobamate*
72. ► **M3** 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. ► **M3** Diphenoxylate* hydrochloride ◀
81. 4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82. Chlorzoxazone*
83. 2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)
84. Chlorprothixene* and its salts
85. Clofenamide*
86. ► **M3** *N,N*-bis(2-chloroethyl)methylamine *N*-oxide and its salts ◀

▼B

87. Chlormethine* and its salts
88. Cyclophosphamide* and its salts
89. Mannomustine* and its salts
90. Butanilicaine* and its salts
91. ►M3 Chlormezanone* ◀
92. Triparanol*
93. 2-[2(4-Chlorophenyl)-2-phenylacetyl] indane-1,3-dione (chlorophacinone-ISO)
94. Chlorphenoxamine*
95. ►M3 2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan 1,3-dione (chlorophacinone - ISO) ◀
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. *Golchicum 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. ►M3 2- α -Cyclohexylbenzyl(*N,N,N',N'*-tetraethyl)trimethylenediamine (phenetamine) ◀
113. Cyclomenol* and its salts
114. Sodium hexacyclonate*
115. Hexapropymate*
116. Dextropropoxyphene*
117. ►M3 *O,O'*-Diacetyl-*N*-allyl-*N*-normorphine ◀
118. Pipazetate* and its salts
119. ►M3 5-($\alpha\beta$ -Dibromophenethyl)-5-methylhydantoin ◀
120. ►M3 *N,N'*-Pentamethylenebis (trimethylammonium salts), e.g. pentamethonium bromide* ◀
121. ►M3 *N,N'*-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, e.g. azamethonium bromide* ◀
122. Cyclarbamate*
123. Clofenotane*; DDT (ISO)
124. ►M3 *N,N'*-Hexamethylenebis(trimethylammonium) salts, e.g. hexamethonium bromide* ◀
125. Dichloroethanes (ethylene chlorides)
126. Dichloroethylenes (acetylene chlorides)
127. Lysergide* and its salts
128. ►M3 2-Diethylaminoethyl-3-hydroxy-4-phenylbenzoate and its salts ◀
129. Cinchocaine* and its salts
130. 3-Diethylaminopropyl cinnamate
131. ►M3 *O,O'*-Diethyl *O*-4-nitrophenyl phosphorothioate (parathion-ISO) ◀
132. ►M3 [Oxalylbisiminoethylene]bis[*o*-chlorobenzyl]diethylammonium salts], e.g. ambenonium chloride* ◀
133. Methyprylon* and its salts
134. Digitaline and all heterosides of *Digitalis purpurea L.*

▼ **B**

135. 7-[2-Hydroxy-3-(2-hydroxyethyl-*N*-methylamino)propyl]theophylline (xanthinol)
136. Dioxethedrin* and its salts
137. Piprocurarium*
138. Propyphenazone*
139. Tetrabenazine* and its salts
140. Captodiame*
141. Mefeclozazine* and its salts
142. Dimethylamine
143. ► **M3** 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. ► **M3** *N*-(3-Carbamoyl-3,3-diphenylpropyl)-*N,N*-diisopropylmethyl-ammonium salts, e.g. isopropamide iodide* ◀
157. Benactyzine*
158. Benzatropine* and its salts
159. Cyclizine* and its salts
160. ► **M3** 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 ► **M9** 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. Methheptazine* and its salts
175. Methylphenidate* and its salts
176. Doxylamine* and its salts
177. Tolboxane*

▼ **M9**

178. 4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol

▼ **B**

179. Parethoxycaine* and its salts
180. Fenozolone*
181. Glutethimide* and its salts
182. Ethylene oxide
183. Bemegride* and its salts

▼ **B**

- 184. Valnoctamide*
- 185. Haloperidol*
- 186. Paramethasone*
- 187. Fluanisone*
- 188. Trifluoperidol*
- 189. Fluoresone*
- 190. Fluorouracil*

▼ **M3**

- 191. Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1

▼ **B**

- 192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*
- 193. Galantamine*
- 194. Progestogens ► **M17** ————— ◀
- 195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)
- 196. ► **M3** (1*R*,4*S*,5*R*,8*S*)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethano-naphthalene (endrin-ISO) ◀
- 197. Hexachloroethane
- 198. (1*R*,4*S*,5*R*,8*S*)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethano-naphthalene (isodrin-ISO)
- 199. Hydrastine, hydrastinine and their salts
- 200. Hydrazides and their salts
- 201. Hydrazine, its derivatives and their salts
- 202. Octamoxin* and its salts
- 203. Warfarin* and its salts
- 204. ► **M3** Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid ◀
- 205. Methocarbamol*
- 206. Propylnitrate*
- 207. ► **M3** 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. ► **M3** 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. ► **M3** α -Santonin [(3*S*,5*aR*,9*bS*)-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

▼ **M11**

- 221. Mercury and its compounds, except those special cases included ► **M18** in Annex VI, Part 1 ◀

▼ **B**

- 222. 3,4,5-Trimethoxyphenethylamine and its salts
- 223. Metaldehyde
- 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. Isomethoprene* and its salts

▼B

- 229. Mecamylamine*
- 230. Guaifenesin*
- 231. Dicoumarol*
- 232. Phenmetrazine*, its derivatives and salts
- 233. Thiamazole*
- 234. ►**M3** 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 metilsulfate*
- 240. Hydroxyzine*
- 241. 2-Naphthol
- 242. 1-and 2-Naphthylamines and their salts
- 243. ►**M3** 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
- 257. Noradrenaline and its salts
- 258. Noscapine* and its salts
- 159. Guanethidine* and its salts
- 260. Oestrogens ►**M15** ————— ◀
- 261. Oleandrin
- 262. Chlortalidone*
- 263. Pelletierine and its salts
- 264. Pentachloroethane
- 265. Pentaerithrityl tetranitrate*
- 266. Petrichloral*
- 267. Octamylamine* and its salts

▼M3

- 268. Picric acid

▼B

- 269. Phenacetamide*
- 270. Difendoxazine*
- 271. ►**M3** 2-Phenylindan-1,3-dione (phenindione) ◀
- 272. Ethylphenacetamide*
- 273. Phenprocoumon*
- 274. Fenylramidol*
- 275. Triamterene* and its salts
- 276. ►**M3** Tetraethyl pyrophosphate; TEPP (ISO) ◀
- 277. Tritolyl phosphate
- 278. Psilocybine*
- 279. Phosphorus and metal phosphides

▼ **B**

- 280. Thalidomide* and its salts
- 281. *Physostigma venenosum* Balf.
- 282. Picrotoxin
- 283. Pilocarpine and its salts
- 284. ► **M3** α -Piperidin-2-ylbenzyl acetate (SIC! 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 ► **M17** compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated ◀
- 290. Coniine
- 291. *Prunus laurocerasus* L. ('cherry laurel water')
- 292. Metyrapone*

▼ **M34**

- 293. Radioactive substances, as defined by Directive 96/29/Euratom⁽¹⁾ laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

▼ **B**

- 294. *Juniperus sabina* L. (leaves, essential oil and galenical preparations)
- 295. Hyoscine, its salts and derivatives
- 296. Gold salts

▼ **M9**

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

▼ **B**

- 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. ► **M3** Sulphonamides (sulphanilamide and its derivatives...) and their salts obtained by substitution of one or more H-atoms of the -NH₂ 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. ► **M3** Xylometazoline* and its salts ◀
- 314. Tetrachloroethylene
- 315. Carbon tetrachloride
- 316. Hexaethyl tetraphosphate
- 317. Thallium and its compounds
- 318. *Thevetia nerifolia* Juss., glycoside extract
- 319. Ethionamide*
- 320. Phenothiazine* and its compounds

⁽¹⁾ OJ L 159, 29.6.1996, p. 1.

▼ **M3**

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

▼ **B**

322. Mephesisin* and its esters
323. Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147, 9. 6. 1975, p. 13)
324. Tranlycypromine* and its salts
325. Trichloronitromethane (chloropicrine)
326. 2,2,2-Tribromoethanol (tribromoethyl alcohol)
327. Trichiormethine* and its salts
328. Tretamine*
329. Gallamine triethiodide*
330. *Urginea scilla Stern.* and its galenical preparations
331. Veratrine, its salts and galenical preparations
332. *Schoenocaulon officinale Lind.* (seeds and galenical preparations)

▼ **M8**

333. *Veratrum Spp.* and their preparations

▼ **B**

334. Vinyl chloride monomer
335. Ergocalciferol* and cholecalciferol (vitamins D₂ and D₃)
336. Salts of *O*-alkyldithiocarbonic acids
337. Yobimbine and its salts
338. Dimethyl sulfoxide*
339. Diphenhydramine* and its salts
340. 4-tert-Butylphenol
341. 4-tert-Butylpyrocatechol
342. Dihydrotachysterol
343. Dioxane
344. Morpholine and its salts
345. *Pyrethrum album L.* and its galenical preparations
346. ► **M3** 2-[4-Methoxybenzyl-*N*-(2-pyridyl)amino]ethyl dimethylamine maleate ◀
347. Tripeleennamine*
348. Tetrachlorosalicylanilides
349. Dichlorosalicylanilides

▼ **M3**

350. Tetrabromosalicylanilides ► **M13** ————— ◀
351. Dibromosalicylanilides ► **M13** ————— ◀

▼ **B**

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

▼ **M24**

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.

▼ **B**

359. Oil from the seeds of *Laurus nobilis L.*

▼ **M3**

360. Safrole except for normal content in the natural essences used and provided the concentration does not exceed:
- 100 ppm in the finished product,

▼ **M3**

50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children

▼ **B**

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

▼ **M32**

362. 3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetoneaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen

▼ **M5**

363. *O*-phenylenediamine and its salts

364. 4-methyl-*m*-phenylenediamine and its salts.

▼ **M32**

365. Aristolochic acid and its salts; *Aristolochia* spp. and their preparations

▼ **M10**

366. Chloroform

▼ **M32**

367. 2,3,7,8-Tetra chlorodibenzo-p-dioxin

▼ **M10**

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

369. Pyrithione sodium (INNM)

▼ **M12**

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

371. 2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)

▼ **M32**

372. 6-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide (minoxidil) and its salts

373. 3,4',5-Tribromosalicylanilide

374. *Phytolacca* spp. and their preparations

▼ **M13**

375. Tretinoin (retinoic acid and its salts)

376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole - CI 76050)
▶ **M17** and their salts ◀

377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) ▶ **M17** and their salts ◀

378. Colouring agent CI 12140

379. Colouring agent CI 26105

380. Colouring agent CI 42555

Colouring agent CI 42555-1

Colouring agent CI 42555-2

▼ **M15**

381. Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))

382. Benzoyl peroxide

383. 2-Amino-4-nitrophenol

384. 2-Amino-5-nitrophenol

▼ **M17**

385. 11 α -Hydroxypregn-4-ene-3,20-dione and its esters

▼ **M32**

385. 11 α -Hydroxypregn-4-ene-3, 20-dione) and its esters

386. Colouring agent C.I. 42 640

▼ **M17**

387. Colouring agent CI 13 065

388. Colouring agent CI 42 535

389. Colouring agent CI 61 554

▼ **M32**

390. Anti-androgens of steroidal structure

▼ M32

- 391. Zirconium and its compounds, with the exception of the substances listed under reference number 50 in Annex III, Part One, and the zirconium lakes, pigments or salts of the colouring agents listed in Annex IV, Part One, with reference number 3
- 393. Acetonitrile
- 394. Tetrahydrozoline and its salts

▼ M18

- 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

▼ M20

- 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

▼ M22

- 412. 4-Amino-2-nitrophenol

▼ M23

- 413. 2-Methyl-m-phenylenediamine

▼ M24

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

▼ M28**▼ M24**

- 416. Cells, tissues or products of human origin
- 417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein*)

▼ M25

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

▼ M29

- 419. ► **M35** From the date referred to in Article 22(1) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽¹⁾, the specified risk materials as designated in Annex V to that Regulation, and ingredients derived therefrom.

Until that date, the specified risk materials as designated in Annex XI Part A to Regulation (EC) No 999/2001, and ingredients derived therefrom. ◀

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

▼ M31

- Transesterification or hydrolysis at at least 200 °C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters),

▼ M29

- Saponification with NaOH 12M (glycerol and soap):
 - Batch process: at 95 °C for three hours
 - or
 - Continuous process: at 140 °C, two bars (2 000 hPa) for eight minutes or equivalent conditions.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

▼ **M28**

420. Crude and refined coal tars

▼ **M30**

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

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

▼ **M34**

423. Alanroot oil (*Inula helenium*) (CAS No 97676-35-2), when used as a fragrance ingredient.

424. Benzyl cyanide (CAS No 140-29-4), when used as a fragrance ingredient.

425. Cyclamen alcohol (CAS No 4756-19-8), when used as a fragrance ingredient.

426. Diethyl maleate (CAS No 141-05-9), when used as a fragrance ingredient.

427. Dihydrocoumarine (CAS No 119-84-6), when used as a fragrance ingredient.

428. 2,4-Dihydroxy-3-methylbenzaldehyde (CAS No 6248-20-0), when used as a fragrance ingredient.

429. 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No 40607-48-5), when used as a fragrance ingredient.

430. 4,6-Dimethyl-8-*tert*-butylcoumarin (CAS No 17874-34-9), when used as a fragrance ingredient.

431. Dimethyl citraconate (CAS No 617-54-9), when used as a fragrance ingredient.

432. 7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No 26651-96-7), when used as a fragrance ingredient.

433. 6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No 141-10-6), when used as a fragrance ingredient.

434. Diphenylamine (CAS No 122-39-4), when used as a fragrance ingredient.

435. Ethyl acrylate (CAS No 140-88-5), when used as a fragrance ingredient.

436. Fig leaf absolute (*Ficus carica*) (CAS No 68916-52-9), when used as a fragrance ingredient.

437. *trans*-2-Heptenal (CAS No 18829-55-5), when used as a fragrance ingredient.

438. *trans*-2-Hexenal diethyl acetal (CAS No 67746-30-9), when used as a fragrance ingredient.

439. *trans*-2-Hexenal dimethyl acetal (CAS No 18318-83-7), when used as a fragrance ingredient.

440. Hydroabietyl alcohol (CAS No 13393-93-6), when used as a fragrance ingredient.

441. 6-Isopropyl-2-decahydronaphthalenol (CAS No 34131-99-2), when used as a fragrance ingredient.

442. 7-Methoxycoumarin (CAS No 531-59-9), when used as a fragrance ingredient.

443. 4-(4-Methoxyphenyl)-3-butene-2-one (CAS No 943-88-4), when used as a fragrance ingredient.

444. 1-(4-Methoxyphenyl)-1-penten-3-one (CAS No 104-27-8), when used as a fragrance ingredient.

445. Methyl *trans*-2-butenate (CAS No 623-43-8), when used as a fragrance ingredient.

446. 7-Methylcoumarin (CAS No 2445-83-2), when used as a fragrance ingredient.

447. 5-Methyl-2,3-hexanedione (CAS No 13706-86-0), when used as a fragrance ingredient.

448. 2-Pentylidenecyclohexanone (CAS No 25677-40-1), when used as a fragrance ingredient.

449. 3,6,10-Trimethyl-3,5,9-undecatrien-2-one (CAS No 1117-41-5), when used as a fragrance ingredient.

450. Verbena oil (*Lippia citriodora* Kunth.) (CAS No 8024-12-2), when used as a fragrance ingredient.

► **C5** 451. Methyleugenol (CAS No 93-15-2) ◀ except for normal content in the natural essences used and provided that the concentration does not exceed:

(a) 0,01 % in fine fragrance

(b) 0,004 % in eau de toilette

▼ **M34**

- (c) 0,002 % in fragrance cream
- (d) 0,001 % in rinse-off products
- (e) 0,0002 % in other leave-on products and oral hygiene products.

ANNEX III

PART I

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

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1a	Boric acid, borates and tetraborates	(a) Talc (b) Products for all hygiene (c) Other products (excluding bath products and hair waving products)	(a) 5 % (by mass/mass as boric acid) (b) 0,1 % (by mass/mass as boric acid) (c) 3 % (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1,5 % (by mass/mass as boric acid) (b) 1. Not to be used in products for children under 3 years of age (c) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1,5 % (by mass/mass as boric acid)	(a) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin (b) 1. Not to be swallowed 2. Not to be used for children under 3 years of age (c) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin
1b	Tetraborates	(a) Bath products (b) Hair waving products	(a) 18 % (by mass/mass as boric acid) (b) 8 % (by mass/mass as boric acid)	(a) Not to be used in products for children under 3 years of age	(a) Not to be used of bathing children under 3 years of age (b) Rinse well

▼ M31

Reference number	Substance	Restrictions			Other limitations and requirements	Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product			
a	b	c	d	e	f	
2a	Thioglycollic acid and its salts	(a) Hair waving or straightening products: — general use — professional use (b) Depilatories (c) Other hair-care products which are removed after application	— 8 % ready for use pH 7 to 9,5 — 11 % ready for use pH 7 to 9,5 — 5 % ready for use pH 7 to 12,7 — 2 % ready for use pH to 9,5 The abovementioned percentages are calculated as thioglycollic acid	(a) (b) (c): The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves ((a) and (c) only)	(a): — Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only (b) and (c): — Contains thioglycolate — Follow the instructions — Keep out of reach of children	
2b	Thioglycollic acid esters	Hair waving or straightening products: — general use — professional use	— 8 % ready for use pH 6 to 9,5 — 11 % ready for use pH 6 to 9,5 The abovementioned percentages are calculated as thioglycollic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — May cause sensitization in the event of skin contact — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves	— Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only	
3	Oxalic acid, its esters and alkaline salts	Hair care products	5 %		For professional use only	
4	Ammonia		6 % calculated as NH ₃		Above 2 %: contains ammonia	
5	Tosylchloramide sodium (*)		0.2 %			

▼ M3

▼ M3

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5 % (b) 3 %		
7	Dichloromethane		35 % (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 %)	0.2 % as maximum impurity content	
8	► M34 m- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-Phenylenediamines (°), with the exception of those derivatives listed <i>elsewhere</i> in this Annex ▼	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	6 % calculated as free base		(a) Can cause an allergic reaction. ► M20 _____ ▼ Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. ► M20 _____ ▼ ► M22 Wear suitable gloves. ▼
9	► M15 Methylphenylenediamines, their N-substituted derivatives and their salts (°) 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. ► M20 _____ ▼ Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. ► M20 _____ ▼ ► M22 Wear suitable gloves. ▼

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
10	Diaminophenols (1)	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. ▶ M20 ————— ▼ Contains diaminophenols. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains diaminophenols. Can cause allergic reaction. ▶ M20 ————— ▼ ▶ M22 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-naire preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	12 % of H ₂ O ₂ (40 volumes), present or released 4 % of H ₂ O ₂ , present or released 2 % of H ₂ O ₂ , present or released 0,1 % of H ₂ O ₂ , present or released		▶ M22 (a): Wear suitable gloves ▼ (a) (b) (c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde (?).

▼ **M3**▼ **M12**▼ **M20**▼ **M3**

▼ M3

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
14	Hydroquinone (3) ▶ M31 ————— ◀	(a) Oxidizing colouring agent for hair-dyeing: 1. General use 2. Professional use (b) ▶ M31 ————— ◀	▶ M31 0,3 % ◀		(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
15a	Potassium or sodium hydroxide ▶ M25 ————— ◀	(a) Nail cuticle solvent (b) Hair straightener 1. General use 2. Professional use (c) pH adjuster — depilatories (d) Other uses as pH adjuster	(a) 5 % by weight (4) (b) 1. 2 % by weight (4) 2. 4,5 % by weight (4) (c) Up to pH 12,7 (d) Up to pH 11		(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children (b) 1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children 2. For professional use only. Avoid contact with eyes. Can cause blindness. (c) Keep out of reach of children. Avoid contact with eyes

▼ M8

▼ M25

▼ **M25**

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15b	Lithium hydroxide	(a) Hair straighteners 1. General use 2. Professional use (b) pH adjuster — for depilatories (c) Other uses — as pH adjuster (for rinse-off products only)	(a) 1. 2 % (*) by weight 2. 4,5 % (*) by weight	(b) pH value not to exceed pH 11 12,7 (c) pH value not to exceed pH 11	(a) 1. Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2. For professional use only Avoid contact with eyes Can cause blindness (b) Contains alkali Keep out of reach of children Avoid contact with eyes
15c	Calcium hydroxide	Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) pH adjuster — for depilatories (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7 % by weight of calcium hydroxide	(b) pH value not to exceed pH 11 12,7 (c) pH value not to exceed pH 11	(a) Contains alkali Avoid contact with eyes Keep out of reach of children Can cause blindness (b) Contains alkali Keep out of reach of children Avoid contact with eyes

▼ **M34**

▼ **M34**

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
16	1-Naphthol (CAS No 90-15-3) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction
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
▶ M20					
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0,5 % calculated as quinine base (b) 0,2 % calculated as quinine base		

▼ **M3**

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
22	Resorcinol ⁽³⁾	(a) Oxidizing colouring agent for hair dyeing 1. general use 2. professional use (b) Hair lotions and shampoos	(a) 5 % (b) 0,5 %		(a) 1. Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them 2. For professional use only. Contains resorcinol. Rinse eyes immediately if product comes into contact with them (b) Contains resorcinol
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2 % calculated as sulphur pH ≤ 12,7 (b) 6 % calculated as sulphur pH ≤ 12,7		(a) Keep out of reach of children. Avoid contact with eyes (b) Keep out of reach of children. Avoid contact with eyes
24	Water-soluble zinc salts with the exception of zinc 4-hydroxybenzenesulphonate and zinc pyrithione		1 % calculated as zinc		
25	Zinc 4-hydroxybenzene sulpho-nate	Deodorants, antiperspirants and astringent lotions	6 % calculated as % of anhydrous substance		Avoid contact with eyes
26	Sodium monofluorophosphate	Oral hygiene products	0,15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains ammonium monofluorophosphate

Reference number	Substance	Restrictions				Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	
27	Sodium monofluorophosphate	Ditto	0,15 % Ditto		Contains sodium monofluorophosphate	
28	Potassium monofluorophosphate	Ditto	0,15 % Ditto		Contains potassium monofluorophosphate	
29	Calcium monofluorophosphate	Ditto	0,15 % Ditto		Contains calcium monofluorophosphate	
30	Calcium fluoride	Ditto	0,15 % Ditto		Contains calcium fluoride	
31	Sodium fluoride	Ditto	0,15 % Ditto		Contains sodium fluoride	
32	Potassium fluoride	Ditto	0,15 % Ditto		Contains potassium fluoride	
33	Ammonium fluoride	Ditto	0,15 % Ditto		Contains ammonium fluoride	
34	Aluminium fluoride	Ditto	0,15 % Ditto		Contains aluminium fluoride	
35	Stannous fluoride	Ditto	0,15 % Ditto		Contains stannous fluoride	
36	Hexadecyl ammonium fluoride	Ditto	0,15 % Ditto		Contains hexadecyl ammonium fluoride	

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

▼ M3

▼ M10

▼ M3

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
46	6-methylcoumarin	Oral hygiene products	0,003 %		
47	Nicomethanol hydrofluoride	Oral hygiene products	0,15 % calculated as F When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains nicomethanol hydrofluoride
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4 %		— Contains silver nitrate — Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Antidandruff shampoos	1 %		— Contains selenium disulphide — Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxyde complexes $Al_2Zr(OH)_4Cl_2$ and the aluminium zirconium chloride hydroxyde glycine complexes	Antiperspirants	20 % as anhydrous aluminium zirconium chloride hydroxide 5,4 % as zirconium	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between two and 10 2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0,9 and 2,1 3. Prohibited in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin

▼ M3

▼ M4

▼ M8

▼ M9

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
51	Quinolín-8-ol and bis (8-hydroxy-quinolium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations	0,3 % calculated as base 0,03 % calculated as base		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % ethanol and isopropyl alcohol		
53	Etidronic acid and its salts (1-hydroxyethylidene-di-phosphonic acid and its salts)	(a) Hair-care (b) Soap	1,5 % expressed as etidronic acid 0,2 % expressed as etidronic acid		▶ M15 ————— ◀
54	1-Phenoxy-propan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %	As a preservative, see Annex VI, Part 1, No 43	
55	Lead acetate	Only for hair-dyeing	0,6 % calculated in lead		Keep away from children. Avoid all contact with the eyes. Wash hands after use. Contains lead acetate. Do not use to dye eyelashes, eyebrows or 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

▼ **M9**▼ **M13**▼ **M12**▼ **M13**▼ **M17**▼ **M18**

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
57	Strontium chloride hexahydrate	(a) Toothpaste (b) Shampoo and face care products	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 % 2,1 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 2,1 %		Contains strontium chloride. Frequent use by children is not advisable
58	Strontium acetate hemihydrate	Toothpaste	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 %		Contains strontium acetate. Frequent use by children is not advisable
59	Talc: Hydrated magnesium silicate	(a) Powdery products intended to be used for children under three years of age (b) other products			► C4 (a) Keep powder away from children's nose and mouth ▼
60	Fatty acid dialkanolamides		Maximum content: 0,5 % dialkanolamine	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Maximum dialkanolamine content: 5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers 	

▼ M18

▼ M30

▼ M20

▼ M23

▼ M20

▼ M20

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
61	Monoalkanolamines		Maximum content: 0,5 % dialkanolamine	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — Maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrite-free containers 	
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2,5 %	(a) (b): <ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrate-free containers 	
63	Strontium hydroxide	pH-regulator in depilatory products	3,5 % calculated as strontium, max. pH of 12,7		<ul style="list-style-type: none"> — Keep out of reach of children — Avoid contact with the eyes
64	Strontium peroxide	Rinse-off hair care preparations professional use	4,5 % calculated as strontium in the ready-for-use preparation	All products must meet the hydrogen peroxide release requirements	<ul style="list-style-type: none"> — Avoid contact with eyes — Rinse eyes immediately if product comes into contact with them — For professional use only — Wear suitable gloves

▼ M23

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
65	Benzalkonium Chloride, bromide and saccharinate	(a) Rinse-off hair (head) care products (b) Other products	(a) 3 % (as benzalkonium chloride) (b) 0,1 % (as benzalkonium chloride)	(a) In the final products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C ₁₄ , or less must not exceed 0,1 % (as benzalkonium chloride)	(a) Avoid contact with the eyes (b) Avoid contact with the eyes
66	Polyacrylamides	(a) Body-care leave-on products (b) Other cosmetic products		(a) Maximum residual acrylamide content 0,1 mg/kg (b) Maximum residual acrylamide content 0,5 mg/kg	
67	Amyl cinnamal (CAS No 122-40-7)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
68	Benzyl alcohol (CAS No 100-51-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ **M23**▼ **M31**▼ **M34**▼ **M37**

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
69	Cinnamyl alcohol (CAS No 104-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
70	Citral (CAS No 5392-40-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
71	Eugenol (CAS No 97-53-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
72	Hydroxy-citronellal (CAS No 107-75-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
73	Isoeugenol (CAS No 97-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
74	Amylcin nanyl alcohol (CAS No 101-85-9)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
75	Benzyl salicylate (CAS No 118-58-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
76	Cinnamal (CAS No 104-55-2)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
77	Coumarin (CAS No 91-64-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
78	Geraniol (CAS No 106-24-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
79	Hydroxy-methylpentylcyclohexanecarboxaldehyde (CAS No 31906-04-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
80	Anisyl alcohol (CAS No 105-13-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
81	Benzyl cinnamate (CAS No 103-41-3)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
82	Farnesol (CAS No 4602-84-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
83	2-(4-tert-Butylbenzyl) propionaldehyde (CAS No 80-54-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
84	Linalool (CAS No 78-70-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
85	Benzyl benzoate (CAS No 120-51-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
86	Citronellol (CAS No 106-22-9)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
87	Hexyl cinnam-aldehyde (CAS No 101-86-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
88	d-Limonene (CAS No 5989-27-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ M37

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
89	Methyl heptin carbonate (CAS No 111-12-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
90	3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one (CAS No 127-51-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
91	Oak moss extract (CAS No 90028-68-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
92	Treemoss extract (CAS No 90028-67-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

▼ **M3**

- (1) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.
- (2) Only if the concentration exceeds 0,05 %.
- (3) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 2.
- **M25** (4) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column d. ▼
- **M34** (5) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1. ▼
- **M34** (6) The concentration 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. ▼

▼ M11

► M14 Part 2 ◀

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
1	Basic Blue 7 (CAS No 2390-60-5)	Non-oxidising colouring agents for hair dyeing	0,2 %		Can cause allergic reaction	30.9.2004
2	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
3	4-Amino-3-nitrophenol (CAS No 610-81-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
4	2,7-Naphthalenediol (CAS no 582-17-2) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004
5	m-Aminophenol (CAS no 591-27-5) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
6	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004

▼ M34

▼ M34

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
7	4-Hydroxypropylamino-3-nitrophenol (CAS No 92952-81-3) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 5,2 % (b) 2,6 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,6 %	(a) (b) Can cause allergic reaction	30.9.2004
8	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts	Non-oxidising colouring agent for hair dyeing	3,0 %		Can cause allergic reaction	30.9.2004
9	HC Blue No 11 (CAS No 23920-15-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
10	Hydroxyethyl-2-nitro-p-toluidine (CAS No 100418-33-5) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	(a) (b) Can cause allergic reaction	30.9.2004
11	2-Hydroxyethylpicramic acid (CAS No 99610-72-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
12	p-Methylaminophenol (CAS No 150-75-4) and its salts	Oxidising colouring agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
13	2,4-Diamino-5-methylphenoxethanol (CAS No 141614-05-3) and its salts	Oxidising colouring agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004

▼ M34

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
14	HC Violet No 2 CAS No 104226-19-9) and its salts	Non-oxidising colouring agent for hair dyeing	2,0 %			30.9.2004
15	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts	Non-oxidising colouring agent for hair dyeing	3,0 %		Can cause allergic reaction	30.9.2004
16	HC Blue No 12 (CAS No 104516-93-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1,5 % (b) 1,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,75 %	(a) (b) Can cause allergic reaction	30.9.2004
17	►C6 2,4-Diamino-5 methyphe-netol (CAS No 113715-25-6) and its salts ◄	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
18	1,3-Bis-(2,4-diaminophenoxy)-propane (CAS No 81892-72-0) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
19	►C6 3-Amino-2,4-dichloro-phenol (CAS No 61693-43-4) and its salts ◄	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
20	Phenyl methyl pyrazolone (CAS No 89-25-8) and its salts	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
21	2-Methyl-5-hydroxyethylamino-phenol (CAS No 55302-96-0) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004

▼ M34

Refer- ence 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
22	Hydroxybenzomorpholine (CAS No 26021-57-8) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
23	1,7-Naphthalenediol (CAS No 575-38-2) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %	Can cause allergic reaction	30.9.2004
24	HC Yellow No 10 (CAS No 109023-83-8) and its salts	Non-oxidising colouring agents for hair dyeing	0,2 %			30.9.2004
25	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3) and its salts	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %	Can cause allergic reaction	30.9.2004
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
27	HC Violet No 1 (CAS No 82576-75-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
28	3-Methylamino-4-nitro-phenox-yethanol (CAS No 59820-63-2) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
29	2-Hydroxy-ethylamino-5-nitro-anisole (CAS No 66095-81-6) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004

▼ M34

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
30	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
31	►C6 HC Red No 13 (CAS No 94158-13-1) and its salts ▼	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,5 % (b) 2,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,25 %		30.9.2004
32	1,5-Naphthalenediol (CAS No 83-56-7) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004
33	Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
34	o-Aminophenol (CAS No 95-55-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
35	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
36	►C6 2,4-Diaminophenox-yethanol (CAS No 66422-95-5) and its salts ▼	Oxidising colouring agents for hair dyeing	4,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,0 %		30.9.2004

▼ M34

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
37	2-Methylresorcinol (CAS No 608-25-3) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
38	4-Amino-m-cresol (CAS No 2835-99-6) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
39	2-Amino-4-hydroxyethylaminonitrosol (CAS No 83763-47-7) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
40	3,4-Diamino-benzoic acid (CAS No 619-05-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
41	6-Amino-o-cresol (CAS No 17672-22-9) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
42	2-Aminomethyl-p-aminophenol (CAS No 79352-72-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
43	Hydroxyethylamino-methyl-p-aminophenol (CAS No 110952-46-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004

▼ M34

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
44	Hydroxyethyl-3,4-methylenedioxyaniline (CAS No 81329-90-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
45	▶C6 Acid Black 52 (CAS No 3618-58-4) and its salts ▼	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
46	2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 % (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 %		30.9.2004
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non-oxidising colouring agents for hair dyeing	2,8 %			30.9.2004
48	3-Nitro-p-hydroxyethylamino-phenol (CAS No 65235-31-6) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 6,0 % (b) 6,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 3,0 %		30.9.2004
49	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
50	HC Red No 10 + HC Red No 11 (CAS No 95576-89-9 + 95576-92-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004

▼ M34

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
51	Yellow No 6 (CAS No 104333-00-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
52	HC Yellow No 12 (CAS No 59320-13-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1,0 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004
53	▶C6 HC Blue No 10 (CAS No 102767-27-1) and its salts ▼	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
54	HC Blue No 9 (CAS No 114087-47-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
55	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
56	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004

▼ M34

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
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non-oxidising colouring agents for hair dyeing	2,0 %			30.9.2004
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non-oxidising colouring agents for hair dyeing	2,0 %			30.9.2004
60	Basic Violet 14 (CAS No 632-99-5) (CI 42510) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 % (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 %		30.9.2004
61	Musk xylene (CAS no 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products			► <u>M36</u> 30.9.2004 ▼
62	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products			► <u>M36</u> 30.9.2004 ▼

▼ **B**

ANNEX IV

▼ **M10**► **M14** PART 1 ◀LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS ⁽¹⁾

Field of application

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		
► M18 — ◀						
12085 ⁽³⁾	Red	X				3 % maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	► M15 — ◀
13015	Yellow	X				E 105
► M13 — ◀						
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E 125
15510 ⁽³⁾	Orange		X			
15525	Red	X				
15580	Red	X				
► M18 — ◀						
15620	Red				X	
15630 ⁽³⁾	Red	X				3 % maximum concentration in the finished product
15800	Red			X		► M15 — ◀
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		

▼ **M10**

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
16255 (3)	Red	X				E 124
16290	Red	X				E 126
17200 ► M17 (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'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20170	Orange			X		
20470	Black				X	► M15 — ◀
21100	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	ditto
21230	Yellow			X		
24790	Red				X	
▼ M20						
26100	Red			X		Purity criteria: aniline ≤ 0,2 % 2-naphthol ≤ 0,2 % 4-aminoazobenzene ≤ 0,1 % 1-(phenylazo)-2-naphthol ≤ 3 % 1-[2-(phenylazo)-phenylazo]-2-naphthalenol ≤ 2 %
▼ M10						
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			► M17 X ◀		► M17 — ◀
42051 (3)	Blue	X				E 131
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	

▼ **M10**

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
42170	Green				X	► M15 — ◀
42510	Violet			X		
42520	Violet				X	5 ppm maximum concentration in the finished product
► M17 — ◀						
42735	Blue			X		
44045	Blue			► M17 X		► M17 — ◀
44090	Green	X				E 142
45100	Red				X	
► M18 — ◀						
► M18 — ◀						
45190	Violet				X	► M15 — ◀
45220	Red				X	
45350	Yellow	X				6 % maximum concentration in the finished product
45370 (3)	Orange	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45380 (3)	Red	X				ditto
45396	Orange	X				when used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 %
45405	Red		X			not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45410 (3)	Red	X				ditto
45425	Red	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 3 % 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45430 (3)	Red	X				E 127 ditto
47000	Yellow			X		► M15 — ◀
47005	Yellow	X				E 104
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				

▼ **M10**

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
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	► M20 ——— ◀
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	► M20 ——— ◀
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				E 160 b
75125	Yellow	X				E 160 d
75130	Orange	X				E 160 a
75135	Yellow	X				E 161 d
75170	White	X				
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
▼ M12 77288	Green	X				free from chromate ion
77289	Green	X				free from chromate ion

▼ **M12**

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾
		1	2	3	4	
▼ M10						
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
▼ M13						
Acid red 195	Red			X		

▼ **B**

- 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.
- (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.

▼ **M10****PART 2****LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS ⁽¹⁾****Field of application**

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	Authorization valid until
		1	2	3	4		
▶ <u>M13</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M20</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M20</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M13</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M17</u> ——— ◀							
▶ <u>M13</u> ——— ◀							
▶ <u>M20</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M20</u> ——— ◀							
▶ <u>M15</u> ——— ◀							
▶ <u>M12</u> ——— ◀							
▶ <u>M13</u> ——— ◀							
▶ <u>M20</u> ——— ◀							

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.

⁽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.

▼B*ANNEX V***LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THE
DIRECTIVE****▼M17** _____**▼M12** _____**▼M17** _____**▼M5** _____**▼M23**

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

▼M17 _____**▼M18** _____**▼M17** _____**▼M10** _____**▼M8** _____

▼ M11*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 %.

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 three years of age, except for shampoos	Not to be used for children under three years of age (!)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (*)	0,6 % (acid)		
5	Formaldehyde paraformaldehyde	0,2 % (except for products for oral hygiene) 0,1 % (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
▶ <u>MI2</u> ▼				
7	Biphenyl-2-ol (o-phenylphenol) and its salts (*)	0,2 % expressed as the phenol		
8	Pyrrithione zinc (INN) (*)	0,5 %	Authorized in products rinsed off Forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogen-sulphites (*)	0,2 % expressed as free SO ₂		
10	Sodium iodate	0,1 %	Rinse-off products only	
11	Chlorobutanol (INN)	0,5 %	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol

▼ **M11**

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
12	4-Hydroxybenzoic acid and its salts and esters (*)	4 % (acid) for 1 ester, 0,8 % (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydracetic acid) and its salts	0,6 % (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt (+)	0,5 % (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0,1 %		
16	Thiomersal (INN)	0,007 % (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0,007 %	For eye make-up and eye make-up remover only	Contains thiomersal
17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (*)	0,2 % (acid)	See Annex VI, Part 2, No 8	
19	Hexetidine (INN) (*)	0,1 %	▶ M13 ————— ▼	
20	5-Bromo-5-nitro-1,3-dioxane	0,1 %	Rinse-off products only Avoid formation of nitrosamines ▶ M15 ————— ▼	
21	Bronopol (INN) (*)	0,1 %	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol (*)	0,15 %		

▼ **M23**▼ **M11**



MI1

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
23	Triclocarban (INN) (*)	0,2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm	
24	4-Chloro-m-cresol (*)	0,2 %	Prohibited in the products intended to come into contact with mucous membranes	
25	Tricolosan (INN) (*)	0,3 %		
26	4-Chloro-3,5-xyleneol (*)	0,5 %		
27	3,3'-Bis (1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methyleneurea ('imidazolidinyl urea') (*)	0,6 %		
28	Poly (1-hexamethylenebiguamide hydrochloride) (*)	0,3 %		
29	2-Phenoxyethanol (*)	1,0 %		
30	Hexamethylenetetramine (*) (methenamine) (INN)	0,15 %		
31	Methenamine 3-chloroallylochloride (INN(M))	0,2 %		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*)	0,5 %		
33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (*)	0,6 %		
34	Benzyl alcohol (*)	1,0 %		
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethyl-2-pyridon and its monoethanolamine salt) (*)	1,0 % 0,5 %	Products rinsed off For other products	

▼ **M11**

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
36	1,2-Dibromo-2,4-dicyanobutane	0,1 %	► M20 Not to be used in cosmetic sunscreen products at a concentration exceeding 0,025 % ▼	
37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen) (*)	0,1 %		
38	4-Isopropyl-m-cresol	0,1 %		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	► M15 0,0015 % ▼ (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one		
40	2-Benzyl-4-chlorophenol (clorophene)	0,2 %		
41	2-Chloroacetamide	0,3 %		Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3 % expressed as clorhexidine		
43	1-Phenoxypropan-2-ol	1,0 %	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (*)	0,1 %		
45	4,4-dimethyl-1,3-oxizalidine	0,1 %	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl)-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0,5 %		

▼ **M12**▼ **M13**▼ **M18**

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
▼ M20 47	1,6-Di (4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (+)	0,1 %		
▼ M23 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 octane [3.3.0]	0,3 %	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
▼ M25 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	
▼ M28 53	Benzethonium chloride	0,1 %	Rinse-off products only	
▼ M30 54	Benzalkonium chloride, bromide and saccharinate (+)	0,1% calculated as benzalkonium chloride		Avoid contact with eyes
▼ M31 55	Benzylformal	0,15 %	Only for products to be removed by rinsing	

▼ **M31**

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
56	3-Iodo-2-propyny/buty/carbamate	0,05 %	1. Not to be used for oral hygiene and lipcare products 2. If the concentration in products intended to remain on the skin exceeds 0,02 % add the phrase: Contains iodine	Contains iodine

▼ **B**

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



M11

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
▶ <u>M15</u> ——— ◀					
▶ <u>M25</u> ——— ◀					
▶ <u>M15</u> ——— ◀					
▶ <u>M18</u> ——— ◀					
▶ <u>M15</u> ——— ◀					
▶ <u>M18</u> ——— ◀					
▶ <u>M13</u> ——— ◀					
▶ <u>M12</u> ——— ◀					
▶ <u>M13</u> ——— ◀					
▶ <u>M12</u> ——— ◀					
▶ <u>M13</u> ——— ◀					
▶ <u>M24</u> ——— ◀					
▶ <u>M30</u> ——— ◀					
▶ <u>M18</u> ——— ◀					
▶ <u>M13</u> ——— ◀					
▶ <u>M15</u> ——— ◀					
▶ <u>M20</u> ——— ◀					

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
▼ <u>M11</u>					
▼ <u>M31</u>					
▼ <u>M11</u>					
▶ <u>M13</u> — — — — ▼					
▶ <u>M15</u> — — — — ▼					
▶ <u>M23</u> — — — — ▼					
▼ <u>M31</u>					
▼ <u>M25</u>					

▼M7*ANNEX VII***List of UV filters which cosmetic products may contain**

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

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

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

PART 1

List of permitted UV filters which cosmetic products may contain

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	4-Aminobenzoic acid	5 %		
2	<i>N,N,N'</i> -Trimethyl-4-(2-oxobom-3-ylidene-methyl) anilinium methyl sulphate	6 %		
3	Homosalate (INN)	10 %		
4	Oxybenzone (INN)	10 %		Contains oxybenzone (!)
▶ <u>M22</u>				
6	2-phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (expressed as acid)		
7	3,3'-(1,4-Phenylenedimethylene) bis (7, 7-dimethyl-2-oxobicyclo-[2,2,1]hept-1-yl-methanesulphonic acid) and its salts	10 % (expressed as acid)		
8	1-(4-tert-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5 %		
9	alpha-(2-Oxobom-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)		
▼ <u>M23</u>				
▼ <u>M22</u>				
▼ <u>M23</u>				
▼ <u>M24</u>				

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
▼ M25 11	Polymer of N-(2 and 4)-(2-oxoborn-3-ylidene)methyl]benzyl]acrylamide	6 %		
▼ M28 12	Octyl methoxycinnamate	10 %		
▼ M30 13	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA)	10 %		
14	Isopentyl-4-methoxycinnamate (Isoamyl p-Methoxycinnamate)	10 %		
15	2,4,6-Triamino-(p-Carbo-2'-Ethylhexyl-1'-Oxy)-1,3,5-Triazine (Octyl Triazone)	5 %		
16	Phenol,2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetramethyl-1-(Trimethylsilyloxy)-Disiloxany))Propyl (Drometrizole Trisiloxane)	15 %		
17	Benzoic acid, 4,4-((6-(((1,1-dimethylethylamino)carbonyl)phenylamino) 1,3,5-triazine-2,4-diyldiimino)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 %		
▼ M31 21	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8 %		

▼ **M31**

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt	5 % (of acid)		
23	2,2'-Methylene-bis-6-(2H-benzotriazol-2yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol	10 %		
24	Monosodium salt of 2,2'-bis-(1,4-phenylene)1H-benzimidazole-4,6-disulphonic acid	10 % (of acid)		
25	(1,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexyloxy)-2-hydroxy-phenyl)-6-(4-methoxy-phenyl))	10 %		
26	Dimethicodiethylbenzalmalonate (CAS No 207574-74-1)	10 %		
27	Titanium dioxide	25 %		

▼ **M34**▼ **M7**

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

▼ M15

PART 2

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

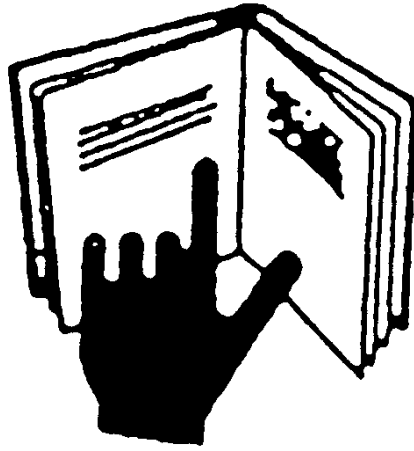
Reference number a	Substances b	Maximum authorized concentration c	Other limitations and requirements d	Conditions of use and warnings which must be printed on the label e	Allowed until f
▶ <u>M20</u> ———— ▼					
▶ <u>M30</u> ———— ▼					
▶ <u>M20</u> ———— ▼					
▼ <u>M31</u> —————					
▼ <u>M15</u> —————					
▶ <u>M30</u> ———— ▼					
▶ <u>M30</u> ———— ▼					
▶ <u>M28</u> ———— ▼					
▶ <u>M20</u> ———— ▼					
▼ <u>M31</u> —————					
▼ <u>M15</u> —————					
▶ <u>M23</u> ———— ▼					
▶ <u>M30</u> ———— ▼					
▶ <u>M30</u> ———— ▼					
▶ <u>M23</u> ———— ▼					
▼ <u>M31</u> —————					
▼ <u>M15</u> —————					
▶ <u>M22</u> ———— ▼					
▶ <u>M30</u> ———— ▼					

▼ **M15**

Reference number	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
► M25 —					

▼ M21

ANNEX VIII



▼M37*ANNEX VIIIa*

An Annex VIIIa shall be added, consisting of a symbol representing an open cream jar. The Commission shall, in accordance with the procedure referred to in Article 10(2) establish this symbol by 11 September 2003 at the latest.