

L.N. 424 of 2004**PRODUCT SAFETY ACT, 2001
(ACT NO. V OF 2001)****Cosmetic Products Regulations, 2004**

IN exercise of the powers conferred by article 39 of the Product Safety Act, 2001, the Minister for Competitiveness and Communications has, on the advice of the Malta Standards Authority, made the following regulations:

1.1 These regulations may be cited as the Cosmetic Products Regulations, 2004. Citation and commencement.

1.2 These regulations shall come into effect upon publication, provided that:

1.2.1 cosmetic products which do not comply with regulation 6.1(c)(iii) or with regulation 6.4 of these regulations but which comply with the Cosmetic Products Regulations, 2002 (L.N. 143 of 2002) may continue to be placed on the market until 11th March 2005 and sold or disposed of to the final consumer until stocks are exhausted;

1.2.2 products which do not comply with the following entries in the Schedules but which comply in all other respects with these regulations and with any corresponding entries in the Schedules to the Cosmetic Products Regulations, 2002, may continue to be placed on the market until the 24th March, 2005 and sold or disposed of to the final consumer until the 24th September 2005:

- Reference No 178 in the Second Schedule,
- Reference No 382 in the Second Schedule,
- Reference No 411 in the Second Schedule,
- Reference No 14 in the Third Schedule, Part I,
- References No 60, 61 and 62 in the Third Schedule, Part I,
- Reference No 36 in the Fifth Schedule, Part I

1.3 These regulations implement the provisions of Council Directive 76/768/EEC of the 27th July, 1976, as amended by:

- Council Directive 79/661/EEC of 24 July, 1979
- Commission Directive 82/147/EEC of 11 February, 1982
- Council Directive 82/368/EEC of 17 May, 1982
- Commission Directive 83/191/EEC of 30 March, 1983
- Commission Directive 83/341/EEC of 29 June, 1983
- Commission Directive 83/496/EEC of 22 September, 1983
- Council Directive 83/574/EEC of 26 October, 1983
- Commission Directive 84/415/EEC of 18 July, 1984
- Commission Directive 85/391/EEC of 16 July, 1985
- Commission Directive 86/179/EEC of 28 February, 1986
- Commission Directive 86/199/EEC of 26 March, 1986
- Commission Directive 87/137/EEC of 2 February, 1987
- Commission Directive 88/233/EEC of 2 March, 1988
- Council Directive 88/667/EEC of 21 December, 1988
- Commission Directive 89/174/EEC of 21 February, 1989
- Council Directive 89/679/EEC of 21 December, 1989
- Commission Directive 90/121/EEC of 20 February, 1990
- Commission Directive 91/184/EEC of 12 March, 1991
- Commission Directive 92/8/EEC of 18 February, 1992
- Commission Directive 92/86/EEC of 21 October, 1992
- Council Directive 93/35/EEC of 14 June, 1993
- Commission Directive 93/47/EEC of 22 June, 1993
- Commission Directive 94/32/EC of 29 June, 1994
- Commission Directive 95/34/EC of 10 July, 1995
- Commission Directive 96/41/EC of 25 June, 1996
- Commission Directive 97/1/EC of 10 January, 1997
- Commission Directive 97/18/EC of 17 April, 1997
- Commission Directive 97/45/EC of 14 July, 1997
- Commission Directive 98/16/EC of 5 March, 1998
- Commission Directive 98/62/EC of 3 September, 1998
- Commission Directive 2000/6/EC of 29 February, 2000
- Commission Directive 2000/11/EC of 10 March, 2000
- Commission Directive 2000/41/EC of 19 June, 2000
- Commission Directive 2002/34/EC of 15 April, 2002
- Commission Directive 2003/1/EC of 6 January, 2003
- Commission Directive 2003/16/EC of 19 February, 2003
- Directive 2003/15/EC of the European Parliament and of the Council of 27 February, 2003
- Commission Directive 2003/80/EC of 5 September, 2003
- Commission Directive 2003/83/EC of 24 September, 2003.

Applicability.

2.1 These regulations shall apply to all cosmetic products as defined in regulation 3.1.1.

2.2 Without prejudice to paragraph 3.1.1, the products to be considered as cosmetic products within the meaning of this definition are listed in the First Schedule to these regulations.

3.1 In these regulations, unless the context otherwise requires, ^{Interpretation.} the following definitions shall apply:

3.1.1 “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;

3.1.2 “Directive” shall mean Directive 76/768/EEC of the European Community;

3.1.3 “Competent authority” for the purposes of regulation 6.8 and regulation 7 shall refer to the Directorate responsible for cosmetic products within the Malta Standards Authority;

3.1.4 “OECD” shall mean the Organization for Economic Cooperation and Development;

3.1.5 “animals” shall mean vertebrate animals;

3.1.6 “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;

3.1.7 “prototype” means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or fully developed.

4.1 A cosmetic product put on the market 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 market. The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in these regulations. ^{General Requirements.}

5.1 Only cosmetic products that conform to the provisions of these regulations may be placed on the market.

5.2 Without prejudice to the general obligations laid down in paragraph 4.1, the use in cosmetic products of the following substances is prohibited:

- (a) substances listed in the Second Schedule;
- (b) substances listed in the Third Schedule, beyond the limits and outside the conditions laid down;
- (c) colouring agents other than those listed in the Fourth Schedule, with the exception of cosmetic products containing colouring agents intended solely to colour hair;
- (d) colouring agents listed in the Fourth Schedule, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;
- (e) preservatives other than those listed in the Fifth Schedule;
- (f) preservatives listed in the Fifth Schedule, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product;
- (g) UV filters other than those listed in the Sixth Schedule;
- (h) UV filters listed in the Sixth Schedule, beyond the limits and outside the conditions laid down therein.

5.3 Without prejudice to the general obligations deriving from regulation 4, the following are prohibited:

- (a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of these regulations, 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 these regulations, 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 of animal testing of finished cosmetic products in order to meet the requirements of these regulations;

(d) the performance of animal testing of ingredients or combinations of ingredients in order to meet the requirements of these regulations, 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 the 27th June, 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances or in the Tenth Schedule of these regulations.

5.4 The presence of traces of the substances listed in the Second Schedule shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms to paragraph 4.1.

6.1 Cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering, provided that the information mentioned in point (g) may, however, be indicated on the packaging alone:

Labelling of
cosmetic products.

(a) the name or style and the address or registered office of the manufacturer or importer or the person responsible for marketing the cosmetic product who is established within the European Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. The country of origin shall be specified for goods not manufactured in the European Community;

(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with paragraph 4.1.

(i) The date of minimum durability shall be indicated by the words: “best before the end of” followed by either:

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

(ii) 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 that must be satisfied to guarantee the stated durability.

(iii) 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 the Ninth Schedule followed by the period (in months and/or years).;

(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 the Third, Fourth, Fifth and Sixth Schedules, which must appear on the container and packaging as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in the Seventh Schedule, which must appear on the container and the packaging;

(e) the batch number of manufacture or the reference for identifying the goods, provided that where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;

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

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

6.2 The particulars provided for in paragraphs 6.1 (d) and (f), if required, must at least be expressed in Maltese or English.

6.3 The following shall not be regarded as ingredients for the purposes of these regulations:

- 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.

6.4 Perfume and aromatic compositions and their raw materials shall be referred to by the word “parfum” or “aroma”. However, the presence of substances, the mention of which is required under the column ‘other limitations and requirements’ in the Third Schedule, shall be indicated in the list irrespective of their function in the product.

6.5 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 the Fourth Schedule.

6.6. 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.

6.7 An ingredient must be identified by the common name given in the International Nomenclature of Cosmetic Ingredients (INCI) and pursuant to Commission Decision 96/335/EC, as amended, or, where such common name does not exist, by one of the following names:

- (i) its chemical name, or
- (ii) its CTFA name, or
- (iii) its European Pharmacopoeia name, or

- (iv) its international non-proprietary name recommended by the World Health Organisation, or
- (v) its EINECS number, or
- (vi) its IUPAC number, or
- (vii) its CAS number, or
- (viii) its colour index number.

6.8. A manufacturer may, for reasons of trade secrecy, not include one or more ingredients on the list mentioned in paragraph 6.1 provided that the competent authority has granted such an authorisation or is satisfied that an authorisation for such omission has been granted. In all cases, the authorization must be given in accordance with the procedure laid down in Commission Directive 95/17/EC.

6.9 Where it is impracticable, for reasons of size or shape, for the particulars referred to in paragraphs 6.1(d) and 6.1(g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card that is enclosed or attached to the cosmetic product.

6.10 In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in paragraph 6.1 (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.

6.11 For cosmetic products which are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, the seller shall make available to the purchaser, on request, a leaflet or similar document, containing the particulars referred to in paragraph 6.1.

6.12 No text, names, trade marks, pictures and figurative or other signs may be used in the labelling, putting up for sale and advertising of cosmetic products so as to imply that these products have characteristics which they do not have. 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.

Information to be kept accessible.

7.1 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 market shall for control purposes keep the following information readily accessible to the competent authority at a specified address:

(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfume, the name and code number of the composition and the identity of the supplier;

(b) the physicochemical 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 Maltese law; the person responsible for manufacture or importation must possess an appropriate level of professional qualification or experience;

(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;

(e) the name and address of the qualified person or persons responsible for the assessment referred to in (d), which person must hold a first degree or equivalent qualification 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;

(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.

Provided that -

7.1.1 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 places so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible; and

7.1.2 without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the information required under regulation 7.1, points (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.

7.2 The assessment of the safety for human health referred to in paragraph 7.1(d) shall be carried out in accordance with the principle of good laboratory practice laid down in the Good Laboratory Practice Regulations, 2004.

7.3 The information referred to in paragraph 7.1 must be available in Maltese or English or Italian.

7.4 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 market, shall notify the competent authority of the address of the place of manufacture or of importation of the cosmetic products before the latter are placed on the market, provided that such notification shall not be necessary in the case of products which have already been placed on the market within the European Community.

7.5 The person placing a cosmetic product on the market shall ensure that he is in possession, or has access to, appropriate and adequate information on substances used in that product. Such information shall be made available on request to the competent authority or to any other

person or body indicated by the competent authority for the purposes of prompt and appropriate medical treatment in the event of difficulties.

7.6 The competent authority or any person or body indicated under paragraph 7.5 shall ensure that any information received is used only for the purposes of such treatment.

8.1 The competent authority may, on the basis of a substantiated justification and on the advice of the Directorate responsible for cosmetic products within the Malta Standards Authority, provisionally prohibit or subject to special conditions the marketing of a cosmetic product which, although complying with the requirements of these regulations, represents a hazard to health.

Provisional
prohibition of
marketing.

8.2 When placing any restriction or ban on the marketing of cosmetic products pursuant to paragraph 8.1, the competent authority shall state precise reasons for any individual measures. Such reasons shall be notified to the party concerned together with particulars of the remedies available to him under Maltese law and of the time limits allowed for the exercise of such remedies.

9.1 Where an official test method is given in the Eighth Schedule, then that method shall be used for the official testing of cosmetic products in accordance with the methods described in the Eighth Schedule.

Methods of
analysis.

10.1 The Cosmetic Products Regulations, 2002 (L.N. 143 of 2002) are hereby repealed.

Repeal of L.N. 143
of 2002.

FIRST SCHEDULE

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,
 - cleaning 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 eyes.
- Products intended for application to the lips.
- Products for the 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.

SECOND SCHEDULE**List of substances which must not form part of the composition of cosmetic products**

(*) In this Schedule, 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.

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. 2-Acetoxyethyl trimethyl ammonium hydroxide (acetylcholine and its salts)
3. Deanol aceglumate*
4. Spironolactone*
5. [4-(4-hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts
6. Methotrexate*
7. Aminocaproic acid* and its salts
8. Cinchophen*, its salts, derivatives and salts of these derivatives
9. Thyropropic acid* and its salts
10. Trichloroacetic acid
11. *Aconitum napellus* L. (leaves, roots and galenical preparations)
12. Aconitine (principal alkaloid of *Aconitum napellus* L.) and its salts
13. *Adonis vernalis* L. and its preparations
14. Epinephrine*
15. *Rauwolfia serpentina* alkaloids and their salts
16. Alkyne alcohols, their esters, ethers and salts
17. Isoprenaline*
18. Allyl isothiocyanate
19. Alloclamide* and its salts
20. Nalorphine*, its salts and ethers
21. Sympathicomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe
22. Aniline, its salts and its halogenated and sulphonated derivatives
23. Butoxycaine* and its salts
24. Zoxazolamine*
25. Procainamide*, its salts and derivatives
26. Benzidine
27. Tuaminoheptane*, its isomers and salts
28. Octodrine* and its salts
29. 2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts
30. 1,3-dimethylpentylamine and its salts
31. 4-Aminosalicylic acid and its salts
32. Toluidines, their isomers, salts and halogenated and sulphonated derivatives
33. Xylidines, their isomers, salts and halogenated and sulphonated derivatives
34. Imperatorin (9-(3-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
40. Antimony and its compounds
41. *Apocynum cannabinum* L. and its preparations
42. Apomorphine (R5,6,6a 7-tetrahydro-6-methyl-4H-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
46. Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Part 1 of the Third Schedule and lakes and pigments prepared from the colouring agents listed with reference (8) in the Fourth Schedule.
47. Benzene
48. 4,5-Dihydrobenzimidazol-4-one

49. Benzazepines and benzadiazepines
50. 1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts (amylocaine)
51. 2,2,6-Trimethyl-4-piperidyl benzoate and its salts (benzamine)
52. Isocarboxazid*
53. Bendroflumethiazide* and its derivatives
54. Beryllium and its compounds
55. Bromine, elemental
56. Bretylium tosylate*
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. (1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
71. Phenprobamate*
72. Nitroderivatives of carbazol
73. Carbon disulphide
74. Catalase
75. Cephaeline and its salts
76. *Chenopodium ambrosioides* (essential oil)
77. 2,2,2-Trichloroethane-1,1-diol
78. Chlorine
79. Chlorpropamide*
80. Diphenoxylate* (hydrochloride)
81. 4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82. Chlorzoxazone*
83. 2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)
84. Chlorprothixene* and its salts
85. Clofenamide*
86. N,N-bis (2-chloroethyl) methylamine N-oxide and its salts
87. Chlormethine* and its salts
88. Cyclophosphamide* and its salts
89. Mannomustine* and its salts
90. Butanilicaine* and its salts
91. Chloromezanone*
92. Triparanol*
93. 2-[2(4-Chlorophenyl)-2-phenylacetyl]indane-1,3-dione (chlorophacinone-ISO)
94. Chlorphenoxamine*
95. Phenaglycodol*
96. Chloroethane
97. Chromium, chromic acid and its salts
98. *Claviceps purpurea Tul.*, its alkaloids and gelanical preparations
99. *Conium maculatum L.* (fruit, powder, gelanical preparations)
100. Glycyclamide*
101. Cobalt benzenesulphonate
102. Colchicine, its salts and derivatives
103. Colchicoside and its derivatives³
104. *Colchicum autumnale L.* and its galenical preparations
105. Convallotoxin
106. *Anamirta cocculus L.* (fruit)
107. *Croton tiglium* (oil)

- 108.1-Butyl-3-(N-crotonoylsulphanilyl)urea
109. Curare and curarine
110. Synthetic curarizants
111. Hydrogen cyanide and its salts
- 112.2- α -Cyclohexylbenzyl (N N N' N'-tetraethyl)trimethylenediamine (phenetamine)
113. Cyclomenol* and its salts
114. Sodium hexacyclonate*
115. Hexapropymate*
116. Dextropropoxyphene*
117. O O-Diacetyl-N-allyl-N-normorphine
118. Pipazetate* and its salts
- 119.5-(α,β -dibromo-phenethyl)-5-methylhydantoin
120. N N-Pentamethylenebis (trimethylammonium salts) e.g. Pentamethonium bromide*
121. N N'-[Methylimino diethylene] bis (ethyldimethylammonium salts), e.g. azamethonium bromide*
122. Cyclobamate*
123. Clofenotane*; DDT (ISO)
124. Hexamethylenebis (trimethylammonium salts), e.g. hexamethonium bromide*
125. Dichloroethanes (ethylene chlorides)
126. Dichloroethylenes (acetylene chlorides)
127. Lysergide* and its salts
- 128.2-Diethylaminoethyl-3-hydroxy-4-phenylbenzoate and its salts
129. Cinchocaine* and its salts
- 130.3-Diethylaminopropyl cinnamate
131. O O-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)
- 132.[Oxalylbis(iminoethylene)] bis [(o-chlorobenzyl)diethylammonium salts], e.g. ambenomium chloride*
133. Methypylon* and its salts
134. Digitaline and all heterosides of *Digitalis purpurea* L.
- 135.7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl] theophylline (xanthinol)
136. Dioxethedrin* and its salts
137. Piprocurarium*
138. Propyphenazone*
139. Tetrabenazine* and its salts
140. Captodiame*
141. Mefeclozazine* and its salts
142. Dimethylamine
- 143.1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts (amydricine, alypine)
144. Methapyrilene* and its salts
145. Metamfepramone* and its salts
146. Amitriptylene* and its salts
147. Metformin* and its salts
148. Isosorbide dinitrate*
149. Malononitrile
150. Succinonitrile
151. Dinitrophenol isomers
152. Inproquone*
153. Dimevamide* and its salts
154. Diphenylpyraline* and its salts
155. Sulfinpyrazone*
156. N-(3-Carbamoyl-3,3-diphenylpropyl)-N N-diisopropylmethylammonium salts, e.g. isopropamide iodide*
157. Benactyzine*
158. Benzatropine* and its salts
159. Cyclizine* and its salts
- 160.5,5-Diphenyl-4-imidazolidone
161. Probenecid*
162. Disulfiram*, thiram (ISO)
163. Emetine, its salts and derivatives
164. Ephedrine and its salts
165. Oxanamide* and its derivatives
166. Eserine or physostigmine and its salts

167. Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Schedule VII, Part 2.
168. Choline salts and their esters, e.g. choline chloride
169. Caramiphen* and its salts
170. Diethyl 4-nitrophenyl phosphate
171. Metethoheptazine* and its salts
172. Oxpheneridine* and its salts
173. Ethoheptazine* and its salts
174. Metheptazine* and its salts
175. Methylphenidate* and its salts
176. Doxylamine* and its salts
177. Tolboxane*
178. 4-Benzoyloxyphenol and 4-ethoxyphenol
179. Parethoxycaine* and its salts
180. Fenozolone*
181. Glutethimide* and its salts
182. Ethylene oxide
183. Bemegride* and its salts
184. Valnoctamide*
185. Haloperidol*
186. Paramethasone*
187. Fluanisone*
188. Trifluoperidol*
189. Fluoresone*
190. Fluorouracil*
191. Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in the Third Schedule.
192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*
193. Galantamine*
194. Progestogens
195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)
196. (1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene (endrin-ISO)
197. Hexachloroethane
198. (1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene (isodrin-ISO)
199. Hydrastine, hydrastinine and their salts
200. Hydrazides and their salts
201. Hydrazine, its derivatives and their salts
202. Octamoxin* and its salts
203. Warfarin* and its salts
204. Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
205. Methocarbamol*
206. Propatyl nitrate*
207. 4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin
208. Fenadiazole*
209. Nitroxoline* and its salts
210. Hyoscyamine, its salts and derivatives
211. *Hyoscyamus niger* L. (leaves, seeds, powder and galenical preparations)
212. Pemoline* and its salts
213. Iodine
214. Decamethylenebis (trimethylammonium salts), e.g. decamethonium bromide*
215. Ipecacuanha (*Cephaelis ipecacuanha* Brot. and related species) (roots, powder and galenical preparations)
216. (2-Isopropylpent-4-enoyl)urea (apronalide)
217. α -Santonin(3S, 5aR, 9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphtho[1,2b]furan-2,8-dione
218. *Lobelia inflata* L. and its galenical preparations
219. Lobeline* and its salts
220. Barbiturates
221. Mercury and its compounds, except those special cases included in the Fifth Schedule

- 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. Isometheptene* and its salts
- 229. Mecamylamine*
- 230. Guaifenesin*
- 231. Dicoumarol*
- 232. Phenmetrazine*, its derivatives and salts
- 233. Thiamazole*
- 234. 3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H-pyrano[3,2-c]-[1] benzopyran-5-one (cyclocoumarol)
- 235. Carisoprodol*
- 236. Meprobamate*
- 237. Tefazoline* and its salts
- 238. Arecoline
- 239. Poldine metilsulfate*
- 240. Hydroxyzine*
- 241. 2-Naphthol
- 242. 1- and 2-Naphthylamines and their salts
- 243. 3-(1-naphthyl)-4-hydroxycoumarin
- 244. Naphazoline* and its salts
- 245. Neostigmine and its salts (e.g. neostigmine bromide*)
- 246. Nicotine and its salts
- 247. Amyl nitrites
- 248. Inorganic nitrites, with the exception of sodium nitrite
- 249. Nitrobenzene
- 250. Nitroresols and their alkali metal salts
- 251. Nitrofurantoin*
- 252. Furazolidone*
- 253. Propane-1,2,3-triyl trinitrate
- 254. Acenocoumarol*
- 255. Alkali pentacyanonitrosylferrate (2-)
- 256. Nitrostilbenes, their homologues and their derivatives
- 257. Noradrenaline and its salts
- 258. Noscaphine* and its salts
- 259. Guanethidine* and its salts
- 260. Oestrogens
- 261. Oleandrin
- 262. Chlortalidone*
- 263. Pelletierine and its salts
- 264. Pentachloroethane
- 265. Pentaerithrityl tetranitrate*
- 266. Petrichloral*
- 267. Octamylamine* and its salts
- 268. Picric acid
- 269. Phenacetamide*
- 270. Difenclozazine*
- 271. 2-Phenylindane-1,3-dione (phenindione)
- 272. Ethylphenacetamide*
- 273. Phenprocoumon*
- 274. Fenyramidol*
- 275. Triamterene* and its salts
- 276. Tetraethylpyrophosphate; TEPP (ISO)
- 277. Tritolyl phosphate
- 278. Psilocybine*
- 279. Phosphorus and metal phosphides
- 280. Thalidomide* and its salts

281. *Physostigma venenosum* Balf.
282. Picrotoxin
283. Pilocarpine and its salts
284. α -Piperidin-2-yl benzyl acetate laevorotatory threoform (Levophacetoperane) and its salts
285. Pipradrol* and its salts
286. Azacyclonol* and its salts
287. Bietamiverine*
288. Butopirine* and its salts
289. Lead and its compounds, with the exception of that mentioned in the Third Schedule, No 55 under the conditions stated
290. Coniine
291. *Prunus laurocerasus* L. ('cherry laurel water')
292. Metyrapone*
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 ionizing radiation.
294. *Juniperus sabina* L. (leaves, essential oil and galenical preparations)
295. Hyoscine, its salts and derivatives
296. Gold salts
297. Selenium and its compounds with the exception of selenium disulphide under the conditions set out under reference No 49 in the Third Schedule
298. *Solanum nigrum* L. and its galenical preparations
299. Sparteine and its salts
300. Glucocorticoids
301. *Datura stramonium* L. and its galenical preparations
302. Strophantines, their aglucones and their respective derivatives
303. *Strophantus* species and their galenical preparations
304. Strychnine and its salts
305. *Strychnos* species and their galenical preparations
306. Narcotics, natural and synthetic: all substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961
307. Sulphonamides (sulphonylamide and its derivatives obtained by substitution of one or more H-atoms of the -NH₂ groups) and their salts
308. Sultiame*
309. Neodymium and its salts
310. Thiotepea*
311. *Pilocarpus jaborandi* Holmes and its galenical preparations
312. Tellurium and its compounds
313. Xylometazoline and its salts
314. Tetrachloroethylene
315. Carbon tetrachloride
316. Hexaethyl tetraphosphate
317. Thallium and its compounds
318. *Thevetia neriifolia* Juss., glycoside extract
319. Ethionamide*
320. Phenothiazine* and its compounds
321. Thiourea and its derivatives, with the exception of the one listed in the Third Schedule
322. Mephesisin* and its esters
323. Vaccines, toxins or serums listed in the Schedule 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. Trancylcypromine* and its salts
325. Trichloronitromethane (chloropicrine)
326. 2,2,2-Tribromoethanol (tribromoethyl alcohol)
327. Trichlormethine* and its salts
328. Tretamine*
329. Gallamine triethiodide*

¹ OJ L 159, 29.6.1996, p.1.

330. *Urginea scilla* Stern. and its galenical preparations
331. Veratrine, its salts and galenical preparations
332. *Schoenocaulon officinale* Lind. (seeds and galenical preparations)
333. *Veratrum* Spp. and their preparations
334. Vinyl chloride monomer
335. Ergocalciferol* and cholecalciferol (vitamins D₂ and D₃)
336. Salts of O-alkyldithiocarbonic acids
337. Yohimbine and its salts
338. Dimethyl sulfoxide*
339. Diphenhydramine* and its salts
340. 4-tert-Butylphenol
341. 4-tert-Butylpyrocatechol
342. Dihydrotachysterol*
343. Dioxane
344. Morpholine and its salts
345. *Pyrethrum album* L. and its galenical preparations
346. 2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyl dimethylamine
347. Tripelennamine*
348. Tetrachlorosalicylanilides
349. Dichlorosalicylanilides
350. Tetrabromosalicylanilides
351. Dibromosalicylanilides
352. Bithionol*
353. Thiuram monosulphides
354. Thiuram disulphides
355. Dimethylformamide
356. 4-Phenylbut-3-en-2-one
357. Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used
358. Furocoumarines (e.g. trioxysalan*, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used.
In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg.
359. Oil from the seeds of *Laurus nobilis* L.
360. Safrole except for normal content in the natural essences used and provided the concentration does not exceed:
100 ppm in the finished product,
50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children
361. 5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite
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
363. O-phenylenediamine and its salts
364. 4-methyl-m-phenylenediamine and its salts
365. Aristolochic acid and its salts; *Aristolochia* spp. and their preparations.
366. Chloroform
367. 2,3,7,8-Tetrachlorodibenzo-p-dioxin
368. 2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)
369. Pyrethione sodium (INN)
370. N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)
371. 2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)
372. 6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (minoxidil) and its salts.
373. 3,4',5-Tribromosalicylanide
374. *Phytolacca* spp. and their preparations
375. Tretinoin* (retinoic acid and its salts)
376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole – CI 76050) and their salts
377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and their salts
378. Colouring agent CI 12140
379. Colouring agent CI 26105
380. Colouring agent CI 42555
- Colouring agent CI 42555-1

- Colouring agent CI 42555-2
381. Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
 382. [deleted]
 383. 2-Amino-4-nitrophenol
 384. 2-Amino-5-nitrophenol
 385. 11 α -Hydroxypregn-4-ene-3,20-dione and its esters
 386. Colouring agent CI 42640
 387. Colouring agent CI 13065
 388. Colouring agent CI 42535
 389. Colouring agent CI 61554
 390. Antiandrogens of steroidal structure
 391. Zirconium and its compounds, with the exception of the substances under reference number 50 in the Third Schedule and the zirconium lakes, salts and pigments of the colouring agents listed with reference number 3 in the Fourth Schedule
 392. Thyrothricine
 393. Acetonitrile
 394. Tetrahydrozoline and its salts
 395. Hydroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in the Third Schedule
 396. Dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) – (pyrithione disulphide + magnesium sulphate)
 397. Colouring agent CI 12075 and its lakes, pigments and salts
 398. Colouring agent CI 45170 and CI 45170:1
 399. Lidocaine
 400. 1,2-Epoxybutane
 401. Colouring agent CI 15585
 402. Strontium lactate
 403. Strontium nitrate
 404. Strontium polycarboxylate
 405. Pramocaine
 406. 4-Ethoxy-m-phenylenediamine and its salts
 407. 2,4-diaminophenylethanol and its salts
 408. Catechol
 409. Pyrogallol
 410. Nitrosamines
 411. Secondary alkyl- and alkanolamines and their salts
 412. 4-Amino-2-nitrophenol
 413. 2-Methyl-m-phenylenediamine
 414. 4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)
 415. [deleted]
 416. Cells, tissues or products of human origin
 417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein*)
 418. 3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)
 419. From the date referred to in Article 22(1) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽²⁾, 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 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:

- transesterification or hydrolysis at at least 200 °C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters),
- Saponification with NaOH 12M (glycerol and soap):
- Batch process at 95 °C for three hours
- or
- Continuous process: at 140 °C, two bars (2000 hPa) for eight minutes or equivalent conditions

² OJ L 147, 31.5.2001, p.1

420. Crude and refined coal tars.
 421. 1,1,3,3,5-Pentamethyl-4,6-dinitroindane (moskene)
 422. 5-*tert*-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene)
 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-butenolate (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.
 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
 - (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.
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List of Substances which Cosmetic Products must not contain except subject to the restrictions and conditions laid down

*) In this Schedule, 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.

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		
1a	Boric acid, borates and tetraborates	(a) Talc	(a) 5% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under three 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 three years of age. 2. Not to be used on peeling or irritated skin.		
		(b) Products for oral hygiene	(b) 0.1% (by mass/mass as boric acid)	(b) 1. Not to be used in products for children under three years of age.	(b) 1. Not to be swallowed. 2. Not to be used in products for children under three years of age.		
		(c) Other products (excluding bath products and hair products)	(c) 3% (by mass/mass as boric acid)	(c) 1. Not to be used in products for children under three years of age.	(c) 1. Not to be used for children under three years of age.		

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	
		waving products)		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)	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 in bathing children under 3 years of age (b) Rinse well	
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	(a) - 8% ready for use, pH : 7-9.5 - 11% ready for use, pH : 7- 9.5 (b) 5% ready for use, pH ≤ 12.7 (c) 2% ready for use pH 7 to 9.5 percentages calculated as thioglycollic acid	(a) (b) (c): The directions for use drawn up in the official languages must obligatorily incorporate the following sentences: - Avoid contact with the eyes - In the event of contact with the eyes, rinse immediately with plenty of water and seek medical advice - Wear suitable gloves (a) and (c) only	(a): - Contains thioglycolate - Follow the instructions - Keep out of reach of children - For professional use only (b) and (c): - Contains thioglycolate - Follow the instructions - Keep out of reach of children	

Reference Number	Substance	Restrictions			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	
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 official languages must obligatorily incorporate the following sentences: - May cause sensitization in the event of skin contact - Avoid contact with the eyes - In the event of contact with the eyes, rinse immediately with plenty of water and seek medical advice - Wear suitable gloves	- Contains thioglycolate - Follow the instructions - Keep out of reach of children - For professional use only	
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%			For professional use only
4	Ammonia		6% calculated as NH ₃			Above 2%: contains ammonia
5	Tosylchloramide sodium*		0.2%			
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%			
7	Dichloromethane		35% (when mixed with 1,1,1-trichloro-ethane, total concentration must not exceed 35%)	0.2% as maximum impurity content		

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	
8	m- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-Phenylenediamines (³), with the exception of those derivatives listed elsewhere in this Schedule.	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	6% calculated as free base		(a) Can cause an allergic reaction. Contains phenylene-diamines. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylene-diamines. Can cause an allergic reaction. Wear suitable gloves.	
9	Methylphenyl-diamines, other N-substituted derivatives and their salts ³	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10% calculated as free base		(a) Can cause an allergic reaction. Contains phenylene-diamines. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylene-diamines. Can cause an allergic reaction. Wear suitable gloves.	
10	Diaminophenols ³	Oxidizing colouring	10% calculated as free			

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 authorised for each of them does not exceed 1.

Reference Number		Substance	Restrictions			Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product		e	f
			c	d			
			agents for hair dyeing (a) general use (b) professional use	base			(a) Can cause an allergic reaction. Contains diaminophenols. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains diaminophenols. Can cause an allergic reaction. Wear suitable gloves.
11		Dichlorophen*		0.5%			Contains dichlorophen
12		Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair care products (b) Skin care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% H ₂ O ₂ (40 volumes) present or released (b) 4% of H ₂ O ₂ present or released (c) 2% of H ₂ O ₂ present or released (d) 0.1% of H ₂ O ₂ present or released			(a) (b) (c) Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them (a) Wear suitable gloves
13		Formaldehyde	Nail hardeners	5% calculated as formaldehyde			Protect cuticles with grease or oil. Contains formaldehyde ⁴
14		Hydroquinone ⁵	(a) Oxidizing colouring	0.3 %			(a) 1. Do not use to dye

⁴ Only if the concentration exceeds 0.05%.

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label		
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements			
15a	Potassium or sodium hydroxide	a	b	c	d	e	f
		1. general use	agents for hair dyeing	0.02 % (after mixing for use)	Professional use only	eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains hydroquinone.	
							2. professional use
		(b) artificial nail systems					
(a) Nail cuticle solvent	(b) Hair straightener	1. general use	(b) 2% by weight ⁶	(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		

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 authorised for each of them does not exceed 2.

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.

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	2. professional use	2. 4.5% by weight ⁶		reach of children.	
		(c) pH adjuster - depilatories	(c) up to pH 12.7		2. For professional use only. Avoid contact with eyes. Can cause blindness.	
		(d) Other uses as pH adjuster	(d) up to pH 11		(c) Keep out of reach of children. Avoid contact with eyes.	
		(a) Hair straighteners	(a) 1. 2% (⁶)by weight		1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children	
		2. Professional use	2. 4.5% (⁶) by weight		2. For professional use only. Avoid contact with eyes. Can cause blindness	
		(b) pH adjuster – for depilatories		(b) pH value not to exceed pH 12.7	(b) Contains alkali. Keep out of reach of children. Avoid contact with eyes.	
		(c) Other uses – as pH		(c) pH value not to		

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	
15c	Calcium hydroxide	adjuster (for rinse-off products only) (a) Hair straighteners containing 2 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	exceed pH 11 (b) pH value not to exceed pH 12.7 (c) pH value not to exceed pH 11	(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children (b) Contains alkali. Keep out of reach of children. Avoid contact with eyes.	
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	

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	
20	[deleted]	[deleted]	[deleted]		[deleted]	
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base			
22	Resorcinol ⁷	(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	(a) Depilatories	(a) 2% calculated as sulphur, pH ≤ 12.7		(a) Keep out of reach of children. Avoid	

⁷ 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 authorised for each of them does not exceed the value given in column d.

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	
	(b) Alkaline earth sulphides	(b) Depilatories	(b) 6% calculated as sulphur, pH $\leq$ 12.7		contact with eyes. (b) Keep out of reach of children. Avoid contact with eyes.	
24	Water soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrrithione		1% calculated as zinc			
25	Zinc 4-hydroxy-benzene sulphonate	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		Avoid contact with eyes	
26	Ammonium mono-fluorophosphate	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this Schedule, total F concentration must not exceed 0.15%		Contains ammonium monofluoro-phosphate	
27	Sodium mono-fluorophosphate	ditto	0.15% ditto		Contains sodium monofluoro-phosphate	
28	Potassium mono-fluorophosphate	ditto	0.15% ditto		Contains potassium monofluoro-phosphate	
29	Calcium mono-fluorophosphate	ditto	0.15% ditto		Contains calcium monofluoro-phosphate	
30	Calcium fluoride	ditto	0.15% ditto		Contains calcium fluoride	
31	Sodium fluoride	ditto	0.15% ditto		Contains sodium fluoride	
32	Potassium fluoride	ditto	0.15% ditto		Contains potassium fluoride	

Reference Number	Substance	Restrictions			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	
33	Ammonium fluoride	ditto	0.15% ditto		Contains ammonium fluoride	
34	Aluminium fluoride	ditto	0.15% ditto		Contains aluminium fluoride	
35	Stannous fluoride	ditto	0.15% ditto		Contains stannous fluoride	
36	Hexadecyl ammonium fluoride	ditto	0.15% ditto		Contains hexadecyl ammonium fluoride	
37	3-(N-Hexadecyl-N-2-hydroxy-ethylammonio) propylbis (2-hydroxyethyl) ammonium di-fluoride	ditto	0.15% ditto		Contains 3-(N-Hexadecyl-N-2-hydroxy-ethylammonio) propylbis (2-hydroxyethyl) ammonium di-fluoride	
38	NN' N'-Tris(polyoxy-ethylene)-N-hexadecyl-propylenediamine dihydrofluoride	ditto	0.15% ditto		Contains NN' N'-Tris(polyoxy-ethylene)-N-hexadecyl-propylenediamine 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 magnesium fluorosilicate	
44	1,3-Bis(hydroxymethyl)imidazolidene-2-thione	(a) Hair care preparations	(a) Up to 2%	(a) Prohibited in aerosol dispensers (sprays)	Contains 1,3-Bis(hydroxymethyl)imidazolidene-2-thione	

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	
45	Benzyl alcohol	(b) Nair care preparations	(b) up to 2%	(b) The pH of the product as applied must be less than 4		
46	6-methylcoumarin	Solvents, perfumes and flavourings				
47	Nicomethanol hydrofluoride	Oral hygiene products	0.003% 0.15% calculated as F. When mixed with other fluorine compounds permitted under this Schedule, total F concentration must not exceed 0.15%		Contains nicomethanol hydrofluoride	
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		<ul style="list-style-type: none"> - Contains silver nitrate - Rinse the eyes immediately if product comes into contact with them 	
49	Selenium disulphide	Antidandruff shampoos	1%		<ul style="list-style-type: none"> - Contains selenium disulphide - Avoid contact with eyes or damaged skin 	
50	Aluminium zirconium chloride hydroxide complexes $Al_2Zr(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes	Antiperspirants	20% as anhydrous aluminium zirconium chloride hydroxide 5.4% as zirconium	<ol style="list-style-type: none"> 1. The ratio of the number of Al atoms to that of Zr atoms must be between 2 and 10 2. The ratio of the number of (Al+Zr) atoms to that of Cl 	Do not apply to irritated or damaged skin	

Reference Number	Substance	<u>Restrictions</u>				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		
51	Quinolin-8-ol and bis(8-hydroxyqui-nolinium) 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	atoms must be between 0.9 and 2.1 3. Prohibited in aerosol dispensers (sprays)			
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as % of ethanol and isopropyl alcohol				
53	Etidronic acid and its salts (1-hydroxy-ethylidene-di-phosphonic acid and its salts)	(a) Hair care (b) Soap	(a) 1.5% (b) 0.2% expressed as etidronic acid		Contains etidronic acid		
54	1-Phenoxy-propan-2-ol	- Rinse off products only - Prohibited in oral hygiene products	2%	As a preservative, see Fifth Schedule, No 43			
55	Lead acetate	Only for hair-dyeing	0.6% calculated as 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.		

Reference Number	Substance	<u>Restrictions</u>			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	
56	Magnesium fluoride	Dental hygiene products	0.15% calculated as F. When mixed with other F compounds permitted under this Schedule, total F concentration must not exceed 0.15%		Contains magnesium fluoride	
57	Strontium chloride hexahydrate	Toothpaste	3.5% calculated as Sr. When mixed with other Sr products the total Sr content must not exceed 3.5%		Contains strontium chloride. Frequent use by children is not advisable.	
58	Strontium acetate hemihydrate	(a) Toothpaste (b) Shampoos and face care products	(a) 3.5% calculated as Sr. When mixed with other permitted Sr products the total Sr content must not exceed 3.5% (b) 2.1% calculated as Sr. When mixed with other permitted Sr products, the total Sr content must not exceed 2.1%.		Contains strontium chloride. 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			Powder products: Keep powder away from children's nose and mouth	
60	Fatty acid dialkylamides		Maximum secondary	- Do not use with		

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
	and dialkanolamides		amine content: 0.5%	<ul style="list-style-type: none">- nitrosating systems- Maximum secondary amine content: 5% (applies to raw materials)- Maximum nitrosamine content: 50 µg/kg- Keep in nitrite-free containers	
61	Monoalkylamines, monoalkanolamines and their salts		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none">- Do not use with nitrosating systems- Minimum purity: 99%- Maximum secondary amine content: 0.5% (applies to raw materials)- Maximum nitrosamine content: 50 µg/kg- Keep in nitrite-free containers	
62	Trialkylamines, trialkanolamines and their salts	(a) Non-rinse-off products (b) other products	(a) 2.5%	(a) Do not use with nitrosating systems Minimum purity: 99% Maximum secondary amine content: 0.5%	

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	
				(concerns raw materials) - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers		
63	Strontium hydroxide	pH regulator in depilatory products	3.5% calculated as Sr, max. pH of 12.7		- Keep out of reach of children - Avoid contact with eyes	
64	Strontium peroxide	Rinse-off hair care preparations for professional use	4.5% calculated as Sr in the ready-for-use preparation	All products must meet the hydrogen peroxide release requirements	- Avoid contact with eyes - Rinse eyes immediately if product comes into contact with them - For professional use only - Wear suitable gloves	
65	Benzalkonium chloride, bromide and saccharinate	(a) Rinse off hair (head) care products	(a) 3% (as benzalkonium chloride)	(a) In the final products the concentration 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	

Reference Number	Substance	<u>Restrictions</u>			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	
		(b) Other products	(b) 0.1% as benzalkonium chloride		(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 regulation 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 regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products		

Reference Number	Substance	<u>Restrictions</u>			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 regulation 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 regulation 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 regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products	

Reference Number	Substance	<u>Restrictions</u>			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
72	Hydroxy-citronellal (CAS No 107-75-5)				The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products	
73	Isoeugenol (CAS No 97-54-1)				The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products	
74	Amylcin namyl alcohol (CAS No 101-85-9)				The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products	

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
75	Benzyl salicylate (CAS No 118-58-1)			<div>- 0.01 % in rinse-off products</div> <div>The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds:<div>- 0.001 % in leave-on products</div><div>- 0.01 % in rinse-off products</div></div>	
76	Cinnamal (CAS No 104-55-2)			<div>The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds:<div>- 0.001 % in leave-on products</div><div>- 0.01 % in rinse-off products</div></div>	
77	Coumarin (CAS No 91-64-5)			<div>The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds:<div>- 0.001 % in leave-on products</div></div>	

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	
78	Geraniol (CAS No 106-24-1)			products - 0.01 % in rinse-off products The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products		
79	Hydroxy-methylpentyl-cyclohexenecarboxaldehyde (CAS No 31906-04-4)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 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 regulation 6.1(g) when its concentration exceeds:		

		Restrictions			Conditions of use and warnings which must be printed on the label
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
				<ul style="list-style-type: none">- 0.001 % in leave-on products- 0.01 % in rinse-off products	
81	Benzyl cinnamate (CAS No 103-41-3)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: <ul style="list-style-type: none">- 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 regulation 6.1(g) when its concentration exceeds: <ul style="list-style-type: none">- 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 regulation 6.1(g) when its concentration	

Reference Number	Substance	<u>Restrictions</u>				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	
84	Linalool (CAS No 78-70-6)			exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products The presence of the substance must be indicated in the list of ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products		
85	Benzyl benzoate (CAS No 120-51-4)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 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 regulation 6.1(g) when		

Reference Number	Substance	<u>Restrictions</u>				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	
				its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products		
87	Hexyl cinnamaldehyde (CAS No 101-86-0)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 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 regulation 6.1(g) when its concentration exceeds: - 0.001 % in leave-on products - 0.01 % in rinse-off products		
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		

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	
90	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (CAS No 127-51-5)			regulation 6.1(g) when its concentration exceeds: <ul style="list-style-type: none"> - 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 regulation 6.1(g) when its concentration exceeds: <ul style="list-style-type: none"> - 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		

Reference Number	Substance	<u>Restrictions</u>			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	
				ingredients referred to in regulation 6.1(g) when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products		
93	2,4-Diamino-pyrimidine-3-oxide (CAS No 74638-76-9)	Hair care formulations	1,5 %			
94	Benzoyl peroxide	Artificial nail systems	0,7 % (after mixing)	Professional use only	For professional use only. Avoid skin contact. Read directions for use carefully.	
95	Hydroquinone methyl ether	Artificial nail systems	0,02 % (after mixing for use)	Professional use only	For professional use only. Avoid skin contact. Read directions for use carefully.	
96	Musk xylene (CAS No 81-15-2)	All cosmetic products, with the exception of oral hygiene products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products			
97	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral hygiene products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products			

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
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	31.12.2005
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	31.12.2005
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	31.12.2005
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 %		31.12.2005

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
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	31.12.2005
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	31.12.2005
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	31.12.2005
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	31.12.2005
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	31.12.2005

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
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	31.12.2005
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	31.12.2005
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	31.12.2005
13	2,4-Diamino-5-methylphenoxyethanol (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	31.12.2005
14	HC Violet No 2 CAS No 104226-19-9) and its salts	Non-oxidising colouring agent for hair dyeing	2.0 %			31.12.2005
15	Hydroxyethyl-2,6-	Non-oxidising	3.0 %		Can cause allergic	31.12.2005

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
	dinitro-p-anisidine (CAS No 122252-11-3) and its salts	colouring agent for hair dyeing			reaction	
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	31.12.2005
17	2,4-Diamino-5-methylphenetol (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	31.12.2005
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	31.12.2005
19	3-Amino-2,4-dichlorophenol (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	31.12.2005
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		31.12.2005

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
A	B	C	D	E	F	G
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
21	2-Methyl-5-hydroxyethylaminophenol (CAS No 55302-96-0) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	application is 0.25 % In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2005
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	31.12.2005
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	31.12.2005
24	HC Yellow No 10 (CAS No 109023-83-8) and its salts	Non-oxidising colouring agents for hair dyeing	0.2 %			31.12.2005
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	31.12.2005
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2005
27	HC Violet No 1 (CAS No 82576-75-8) and its salts	(a) Oxidising colouring agents for	(a) 0.5 %	In combination with hydrogen peroxide the		31.12.2005

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
		hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %	maximum use concentration upon application is 0.25 %		
28	3-Methylamino-4-nitro-phenoxyethanol (CAS No 59820-63-2) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2005
29	2-Hydroxy-ethylamino-5-nitroanisole (CAS No 66095-81-6) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2005
30	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylene-diamine (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 %		31.12.2005
31	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 %		31.12.2005
32	1,5-Naphthalenediol (CAS No 83-56-7) and its	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the		31.12.2005

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
	salts			maximum use concentration upon application is 0.5 %		
33	Hydroxypropyl bis N-hydroxyethyl-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	31.12.2005
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 %		31.12.2005
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 %		31.12.2005
36	2,4-Diaminophenoxyethanol (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 %		31.12.2005
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		31.12.2005

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
A	B	C	D	E	F	G
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 %		31.12.2005
39	2-Amino-4-hydroxyethylaminoanisole (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 %		31.12.2005
40	3,4-Diaminobenzoic 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 %		31.12.2005
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 %		31.12.2005
42	2-Aminomethyl-paminophenol (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 %		31.12.2005
43	Hydroxyethylamino-methyl-paminophenol (CAS No 110952-46-0)	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2005

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
A	B	C	D	E	F	G
	and its salts			concentration upon application is 1.5 %		
44	Hydroxyethyl-3,4-methylenedioxylaniline (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 %		31.12.2005
45	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 %		31.12.2005
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 %		31.12.2005
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non-oxidising colouring agents for hair dyeing	2.8 %			31.12.2005
48	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for	(a) 6.0 % (b) 6.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 3.0 %		31.12.2005

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
		hair dyeing				
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 %		31.12.2005
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 %		31.12.2005
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 %		31.12.2005
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 %		31.12.2005

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
53	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 %		31.12.2005
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 %		31.12.2005
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 %		31.12.2005
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 %		31.12.2005
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 0.5 %	In combination with hydrogen peroxide the maximum use concentration upon		31.12.2005

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
		(b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %	application is 0.25 %		
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			31.12.2005
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			31.12.2005
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 %		31.12.2005

FOURTH SCHEDULE

List of Colouring Agents allowed for use in Cosmetic Products¹

Field of application

Column 1	Column 2
Column 2	Colouring agents allowed in all cosmetic products.
Column 3	Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes.
Column 4	Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
10006	Green				x	
10020	Green			x		
10316 ³	Yellow		x			
11680	Yellow			x		
11710	Yellow			x		
11725	Orange				x	
11920	Orange	x				
12010	Red			x		
12085 ³	Red	x				3% maximum concentration in the finished product
12120	Red				x	

¹ Lakes or salts of these colouring agents using substances not prohibited under the Second Schedule or not excluded under the Fifth Schedule from the scope of this Order 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 fulfill 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 of the Directive.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
12150	Red	x				
12370	Red				x	
12420	Red				x	
12480	Brown				x	
12490	Red	x				
12700	Yellow				x	
13015	Yellow	x				E 105
14270	Orange	x				E 103
14700	Red	x				
14720	Red	x				E 122
14815	Red	x				E 125
15510 ³	Orange		x			
15525	Red	x				
15580	Red	x				
15620	Red				x	
15630 ³	Red	x				3% maximum concentration in the finished product
15800	Red			x		
15850 ³	Red	x				
15865 ³	Red	x				
15880	Red	x				
15980	Orange	x				E 111
15985 ⁸	Yellow	x				E 110
16035	Red	x				
16185	Red	x				E 123
16230	Orange			x		
16255 ⁸	Red	x				E 124
16290	Red	x				E 126
17200 ⁸	Red	x				
18050	Red			x		
18130	Red				x	
18690	Yellow				x	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
18736	Red				x	
18820	Yellow				x	
18965	Yellow	x				
19140 ^s	Yellow	x				
20040	Yellow				x	E 102 maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20170	Orange			x		
20470	Black				x	
21100	Yellow				x	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				x	ditto
21230	Yellow			x		
24790	Red				x	
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%
27290 ^s	Red				x	
27755	Black	x				E 152
28440	Black	x				E 151
40215	Orange				x	
40800	Orange	x				
40820	Orange	x				
40825	Orange	x				E 160e
40850	Orange	x				E 160f
42045	Blue			x		E 161g
42051 ^s	Blue	x				
42053	Green	x				E 131
42080	Blue				x	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
42090	Blue	x				
42100	Green				x	
42170	Green				x	
42510	Violet			x		
42520	Violet				x	5 ppm maximum concentration in the finished product
42735	Blue			x		
44045	Blue			x		
44090	Green	x				E 142
45100	Red				x	
45190	Violet				x	
45220	Red				x	
45350	Yellow	x				6% maximum concentration in the finished product
45370 ⁸	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 ⁸	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 ⁸	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 ⁸	Red	x				E 127, ditto
47000	Yellow			x		
47005	Yellow	x				E 104
50325	Violet				x	
50420	Black			x		

Colour index number or denomination	Colour	Field of application				4	Other limitations and requirements ²
		1	2	3			
51319	Violet					x	
58000	Red	x					
59040	Green			x			
60724	Violet					x	
60725	Violet	x					
60730	Violet			x			
61565	Green	x					
61570	Green	x					
61585	Blue					x	
62045	Blue					x	
69800	Blue	x					E 130
69825	Blue	x					
71105	Orange				x		
73000	Blue	x					
73015	Blue	x					E 132
73360	Red	x					
73385	Violet	x					
73900	Violet					x	
73915	Red					x	
74100	Blue					x	
74160	Blue	x					
74180	Blue					x	
74260	Green		x				
75100	Yellow	x					
75120	Orange	x					E 160b
75125	Yellow	x					E 160d
75130	Orange	x					E 160a
75135	Yellow	x					E 161d
75170	White	x					
75300	Yellow	x					E 100
75470	Red	x					E 120
75810	Green	x					E 140 and E 141

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
77000	White	x				E 173
77002	White	x				
77004	White	x				
77007	Blue	x				
77015	Red	x				
77120	White	x				
77163	White	x				
77220	White	x				E 170
77231	White	x				
77266	Black	x				
77267	Black	x				
77268:1	Black	x				E 153
77288	Green	x				free from chromate ion
77289	Green	x				free from chromate ion
77346	Green	x				
77400	Brown	x				
77480	Brown	x				E 175
77489	Orange	x				E 172
77491	Red	x				E 172
77492	Yellow	x				E 172
77499	Black	x				E 172
77510	Blue	x				free from cyanide ions
77713	White	x				
77742	Violet	x				
77745	Red	x				
77820	White	x				E 174
77891	White	x				E 171
77947	White	x				
Lactoflavin	Yellow	x				E 101
Caramel	Brown	x				E 150
Capsanthin, capsorubin	Orange	x				E 160c

Colour index number or denomination	Colour	Field of application				Other limitations and requirements ²
		1	2	3	4	
Beetroot red	Red	x				E 162
Anthocyanins	Red	x				E 163
Aluminium, zinc, magnesium and calcium stearates	White	x				
Bromothymol blue	Blue				x	
Bromocresol green	Green				x	
Acid Red 195	Red			x		

FIFTH SCHEDULE

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 concentrations other than those laid down in this Schedule 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 Schedule.
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 Schedule and which release formaldehyde must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.

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⁾
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)	
6	[deleted]			
7	Biphenyl-2-ol (o-polyphenol) 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
12	4-Hydroxybenzoic acid and its salts and esters (*)	0.4% (acid) for 1 ester, 0.8% (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydracetic acid and its salts)	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt (*)	0.5% (acid)		
15	3,3'-Dibromo-4,4'-	0.1%		

⁴ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)			
16	Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorised by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	Contains thiomersal
17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (*)	0.2% (acid)		
19	Hexetidine (INN) (*)	0.1%		
20	5-Bromo-5-nitro-1,3-dioxane	0.1%	Rinse-off products only Avoid formation of nitrosamines	
21	Bronopol (INN) (*)	0.1%	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol (*)	0.15%		
23	Triclocarban (INN) (*)	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene < 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	
24	4-Chloro-m-cresol (*)	0.2%	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan (INN) (*)	0.3%		
26	4-Chloro-3,5-xyleneol (*)	0.5%		
27	3,3'-Bis (1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methyleneurea	0.6%		
28	(“Imidazolidinyl urea”) (*) Poly (1-hexamethyleneguanide)	0.3%		

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	hydrochloride) (*)			
29	2-Phenoxyethanol (*)	1%		
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%		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)-2-pyridone and its methanolamine salt (*)	1.0%	Products rinsed off	
36	1,2-Dibromo-2,4-dicyanobutane (methylbromo glutaronitrile)	0.5% 0.1%	For other products Rinse off products only	
37	6,6-Dibromo-4,4-dichloro-2,2-methylenediphenol (Bromochlorophen) (*)	0.1%		
38	4-Isopropyl-m-cresol	0.1%		
39	Mixture of 5-Chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0.0015% (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one		
40	2-Benzyl-4-chlorophenol (Chlorophene)	0.2%		
41	2-Chloroacetamide	0.3%		Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (*)	0.3% expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol	1.0%	Only for rinse-off products	

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
44	Alkyl (C12-C22) trimethyl ammonium bromide and chloride (*)	0.1%		
45	4,4-dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N'-(dihydroxymethyl)-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0.5%		
47	1,6-Di(4-aminophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (*)	0.1%		
48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)
49	5-Ethyl-3,7-dioxo-1-azabicyclo [3.3.0] octane	0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
50	3-(p-chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
52	Silver chloride deposited on titanium dioxide	0.004% calculated as AgCl	20% AgCl (w/w) on TiO ₂ . Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips.	
53	Benzethonium chloride	0.1%	Rinse-off products only	
54	Benzalkonium chloride, bromide	0.1% calculated as benzalkonium	Not for oral hygiene and lip	Avoid contact with the eyes

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
55	and saccharinate (+) Benzylhemiformal	chloride 0.15%	products Only for products to be removed by rinsing	
56	3-Iodo-2-propynylobutylcarbamate	0.05%	<ol style="list-style-type: none"> Not to be used for oral hygiene and lipcare products If the concentration in products intended to remain on the skin exceeds 0.02% add the phrase: Contains iodine 	Contains iodine.

SIXTH SCHEDULE

List of UV Filters which cosmetic products may contain

For the purposes of these Regulations, UV filters are substances which, contained in cosmetic sunscreen preparations, 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 Schedule.

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

List of permitted UV filters which cosmetic products may contain

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

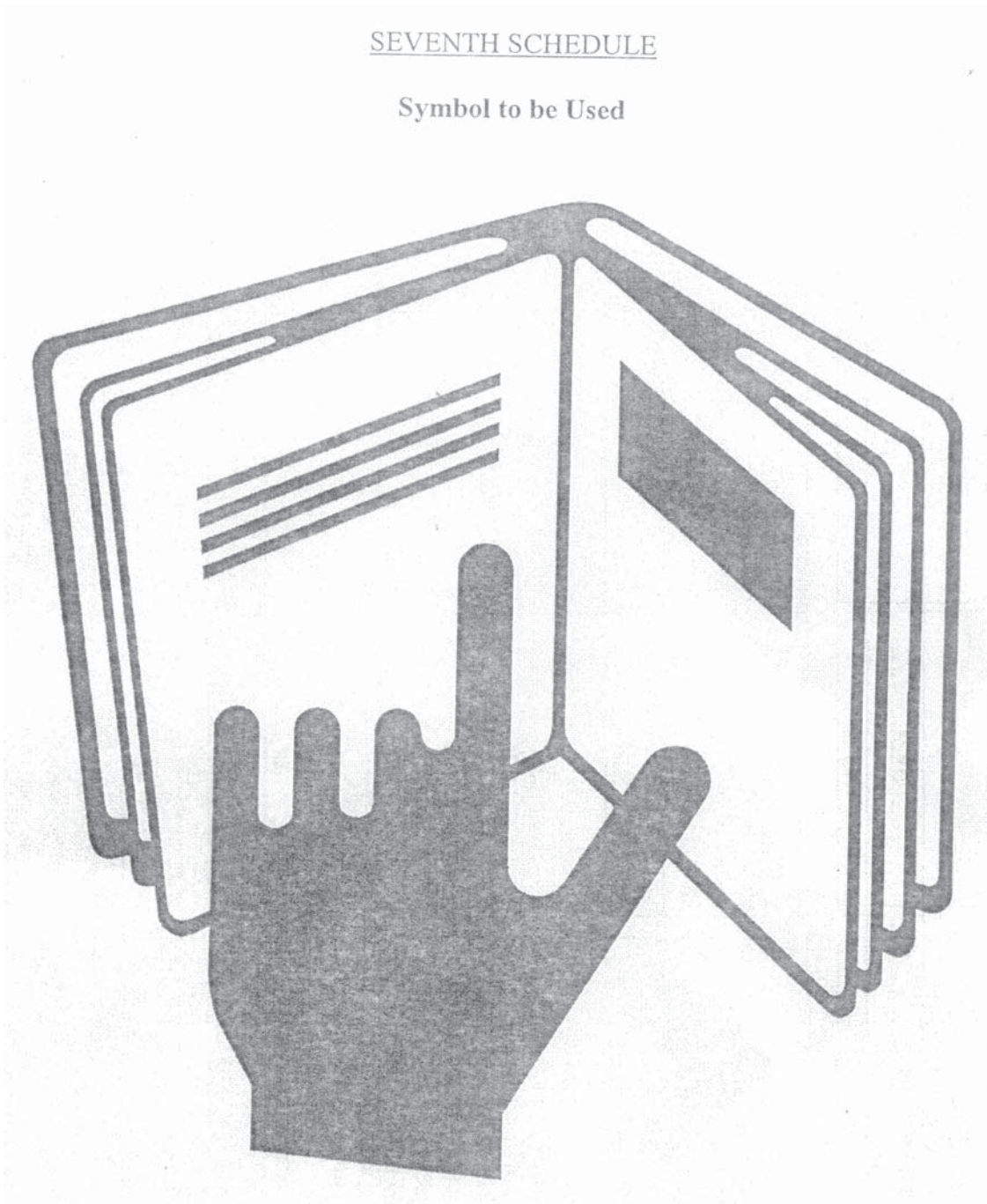
⁵ Not required if concentration is 0.5% or less and when it is used only for product protection purposes.

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
11	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl] benzyl} acrylamide	6%		
12	Octyl methoxycinnamate	10%		
13	Ethoxylated ethyl-4-aminobenzoate (PEG-25 PABA)	10%		
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-tetra-methyl-1-(trimethylsilyl)oxy)-disilo-xanyl)propyl) (Drometrisole Trisiloxane)	15%		
17	Benzoic acid, 4,4-((6-(((1,1-dimethyl-ethyl)amino)carbonyl)phenyl)amino) 1,3,5-triazine-2,4-diyl)diimino)bis-,bis-(2-ethylhexyl)ester)	10%		
18	3-(4'-methylbenzylidene)-d-1 camphor (4-Methylbenzylidene Camphor)	4%		
19	3-Benzylidene camphor (3-Benzylidene Camphor)	2%		
20	2-Ethylhexyl salicylate (octyl-salicylate)	5%		
21	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8%		
22	2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid (Benzophenone-5) and its sodium salt	5% (of acid)		
23	2,2'-Methylene-bis-6-(2H-benzotriazol-2-yl)-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-hexloxy)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl)	10%		

Reference No	<u>Substances</u>	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
26	Dimethicodiethylbenzalmalonate (CAS No 207574-74-1)	10 %		
27	Titanium dioxide	25 %		

SEVENTH SCHEDULE

Symbol to be Used



EIGHTH SCHEDULE

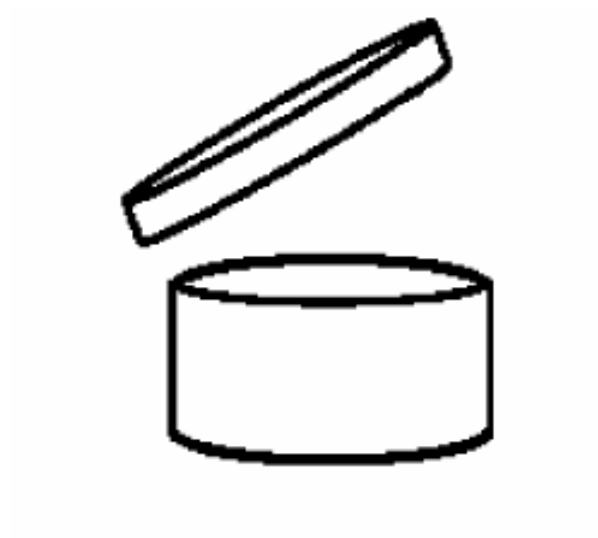
Methods of Analysis necessary for checking the composition of cosmetic products

Area of Analysis	Method to be used
Sampling	Commission Directive 80/1335/EEC, Method I
Laboratory preparation of test samples	Commission Directive 80/1335/EEC, Method II
Identification and determination of free sodium and potassium hydroxides	Commission Directive 80/1335/EEC, Method III
Identification and determination of oxalic acid and alkaline salts in hair care products	Commission Directive 80/1335/EEC, Method IV
Determination of chloroform in toothpastes	Commission Directive 80/1335/EEC, Method V
Determination of zinc	Commission Directive 80/1335/EEC, Method VI, as amended by Commission Directive 87/143/EEC
Identification and determination of phenolsulphonic acid	Commission Directive 80/1335/EEC, Method VII
Identification of oxidizing agents and determination of hydrogen peroxide in hair care products	Commission Directive 82/434/EEC, Method I
Identification and semi-quantitative determination of certain oxidation colorants in hair dyes	Commission Directive 82/434/EEC, Method II
Identification and determination of nitrite	Commission Directive 82/434/EEC, Method III
Identification and determination of free formaldehyde	Commission Directive 82/434/EEC, Method IV, as amended by Commission Directive 90/207/EEC
Determination of resorcinol in shampoos and hair lotion	Commission Directive 82/434/EEC, Method V
Determination of methanol in relation to ethanol or propan-2-ol	Commission Directive 82/434/EEC, Method VI
Determination of dichloromethane and 1,1,1-trichloroethane	Commission Directive 83/514/EEC, Method I
Identification and determination of quinolin-8-ol and bis(8-hydroxyquinolinium) sulphate	Commission Directive 83/514/EEC, Method II
Determination of ammonia	Commission Directive 83/514/EEC, Method III
Identification and determination of nitromethane	Commission Directive 83/514/EEC, Method IV
Identification and determination of mercaptoacetic acid in hair-waving, hair-straightening and depilatory products	Commission Directive 83/514/EEC, Method V
Identification and determination of hexachlorophene (INN)	Commission Directive 83/514/EEC, Method VI
Determination of tosylchloramide, sodium (INN)	Commission Directive 83/514/EEC, Method VII
Determination of total fluorine in dental creams	Commission Directive 83/514/EEC, Method VIII
Identification and determination of organomercury compounds	Commission Directive 83/514/EEC, Method IX
Determination of alkali and alkaline earth sulphides	Commission Directive 83/514/EEC, Method X
Identification and determination of glycerol 1-(4-aminobenzoate)	Commission Directive 85/490/EEC, Method I
Determination of chlorobutanol	Commission Directive 85/490/EEC, Method II
Identification and determination of quinine	Commission Directive 85/490/EEC, Method III

Identification and determination of inorganic sulphites and hydrogen sulphites	Commission Directive 85/490/EEC, Method IV
Identification and determination of chlorates of the alkali metals	Commission Directive 85/490/EEC, Method V
Identification and determination of sodium iodate	Commission Directive 85/490/EEC, Method VI
Identification and determination of silver nitrate	Commission Directive 93/73/EEC, Method I
Identification and determination of selenium disulphide in anti-dandruff shampoos	Commission Directive 93/73/EEC, Method II
Determination of soluble barium and soluble strontium in pigments in the form of salts or lakes	Commission Directive 93/73/EEC, Method III
Identification and determination of benzyl alcohol	Commission Directive 93/73/EEC, Method IV
Identification of zirconium, and determination of zirconium, aluminium and chlorine in non-aerosol antiperspirants	Commission Directive 93/73/EEC, Method V
Identification and determination of hexamidine, dibromohexamidine, dibromopropamidine and chlorhexidine	Commission Directive 93/73/EEC, Method VI
Identification and determination of benzoic acid, 4-hydroxybenzoic acid, sorbic acid, salicylic acid and propionic acid	Commission Directive 95/32/EC, Method I
Identification and determination of hydroquinone, hydroquinone monomethylether, hydroquinone monoethylether and hydroquinone monobenzylether	Commission Directive 95/32/EC, Method II
Identification and determination of 2-phenoxyethanol, 1-phenoxypropan-2-ol and methyl, ethyl, propyl, butyl and benzyl 4-hydroxybenzoate	Commission Directive 96/45/EC

NINTH SCHEDULE

Symbol indicating the durability of cosmetic products



TENTH SCHEDULE

List of Validated Alternative Methods to Animal Testing

This Schedule lists the alternative methods validated by European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Directive and which are not 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 labelling of dangerous substances. As animal testing may not be replaced completely by an alternative method, it should be mentioned in the Tenth Schedule whether the alternative method fully or partially replaces animal testing.

Reference number	Validated alternative methods	Nature of replacement full or partial
A	B	C