L.N. 204 of 2000

QUALITY CONTROL (EXPORTS, IMPORTS AND LOCAL GOODS) ACT (CAP. 225)

Cosmetic Products Order, 2000 (Order No. 47 of 2000)

IN exercise of the powers conferred by article 3 of the Quality Control (Exports, Imports and Local Goods) Act, the Malta Standards Authority has made the following order:-

Citation and commencement.

1.1 The title of this Order is the Cosmetic Products Order, 2000 and may be referred to as Order No. 47 of 2000.

1.2 This Mandatory Order shall come into effect as from 1st January, 2001, provided that:

1.2.1 imported products which have been ordered prior to that date may continue to be marketed until 1st January, 2002, provided that these products comply with the Cosmetics Products Regulations, 1983,

1.2.2 the provisions of this Order shall not apply to cosmetic products manufactured in Malta and marketed prior to 1st July, 2002, provided that these products comply with the Cosmetics Products Regulations, 1983,

1.2.3 the provisions of paragraph 5.2 of this Mandatory Order shall in any case apply to all cosmetic products as from 1st January, 2001.

Applicability.

2.1 This Mandatory Order shall apply to all cosmetic products as defined in this Order.

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 this Order.

Interpretation.1

3.1 In this Order, unless the context otherwise requires, the following definitions shall apply:

3.1.1 "cosmetic product" means 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" means Directive 76/768/EEC of the European Community;

3.1.3 "competent authority" means the Director of Consumer Affairs, provided that the Director may, in writing, authorise any department or other public entity to act as a competent authority for the purposes of notification under paragraph 7.5.

General requirements.

4.1 A cosmetic product put on the market must not cause damage to human health when applied under normal or reasonably forseeable 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 this Order.

Marketing of cosmetic products.

5.1 Only cosmetic products which conform to the provisions of this Order and its Schedules may be put 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 Sixth Schedule;

(f) preservatives listed in the Sixth 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 Seventh Schedule;

(h) UV filters listed in the Seventh Schedule, beyond the limits and outside the conditions laid down therein;

(i) ingredients or combinations of ingredients tested on animals after 30 June 2002 in order to meet the requirements of this Order.

5.3 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 with paragraph 4.1.

Labelling of cosmetic products.

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:

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 Malta or 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 Malta or 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 used before the end of ....." followed by either:

the date itself, or

details of where the date appears on the packaging;

ii) If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied in order to guarantee the stated durability;

iii) The date shall be clearly expressed and shall consist of the month and the year in that order;

iv) Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months;

d) particular precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label" in the Third, Fourth, Sixth and Seventh 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 Eighth 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 Eighth Schedule, which must appear on the container and 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 this Order:

- 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".

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 list of such ingredients is given in square brackets and preceded by the sign "+/-".

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 Pharmacopeia 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 which 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, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.

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 physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

c) the method of manufacture complying with the good manufacturing practice laid down by European Community law or, failing that, laid down by Maltese law; the person responsible for manufacture or importation must hold a first degree or equivalent qualification in the field of pharmacy, chemistry, toxicology, dermatology, medicine or a similar discipline;

d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure;

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.

Provided that:

7.1.1 if the cosmetic product is imported into Malta from within the European Community or if the cosmetic product has already been placed on the market within the European Community, then the importer may, instead of the information required by paragraph 7.1, provide the competent authority with a declaration, signed by the manufacturer or

first importer into the Community, to the effect that the cosmetic product complies with all the requirements of the Directive as well as an indication of the place of initial importation or manufacture within the Community, and that

7.1.2 the qualification requirements for the person responsible for importation laid down by paragraph 7.1(c)shall not apply in the case of cosmetic products imported into Malta from within the European Community or which have already been placed on the market within the European Community.

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 Council Directive 87/18/EEC of 18 December, 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

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 imported from within the European Community or 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.

Provisional prohibition of marketing.

8.1 The competent authority may, on the basis of a substantiated justification, provisionally prohibit or subject to special conditions the marketing of a cosmetic product which, although complying with the requirements of this Order, represents a hazard to health.

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 Ninth Schedule, then that method shall be used for the official testing of cosmetic products in accordance with the methods described in the Ninth Schedule. Methods of analysis.

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. Betoxycaine* 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-methoxylbut-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 tosilate*
57. Carbromal*
58. Bromisoval*
59. Brompheniramine* and its salts
60. Benzilonium bromide*
61. Tetrylammonium bromide*
62. Brucine
63. Tetracaine* and its salts
64. Mofebutazone*
65. Tolbutamide*
66. Carbutamide*
67. Phenylbutazone*
68. Cadmium and its compounds
69. Cantharides, *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-methylpyrimdin-4-yldimethylamine (crimidine-ISO)
84. Chlorprothixene* and its salts
85. Clofenamide*
86. N,N-bis (2-chloroethyl) methylamine N-oxide and its salts
87. Chlormethine* and its salts
88. Cyclophosphamide* and its salts
89. Mannomustine* and its salts
90. Butanilicaine* and its salts
91. 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 derivatives
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,ß-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. Cyclarbamate*
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. Methyprylon* and its salts
134. Digitaline and all heterosides of *Digitalis purpurea L.*
135. 7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl] theophylline (xanthinol)
136. Dioxethedrin* and its salts
137. Piprocurarium*
138. Propyphenazone*
139. Tetrabenazine* and its salts
140. Captodiame*
141. Mefeclorazine* and its salts
142. Dimethylamine
143. 1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts (amydricaine, 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-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol
179. Parethoxycaine* and its salts
180. Fenozolone*
181. Glutethimide* and its salts
182. Ethylene oxide
183. Bemegride* and its salts
184. Valnoctamide*
185. Haloperidol*
186. Paramethasone*
187. Fluanisone*
188. Trifluperidol*
189. Fluoresone*
190. Fluorouracil*
191. Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in 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-dimethanonapthalene (isodrin-ISO)
199. Hydrastine, hydrastinine and their salts
200. Hydrazides and their salts
201. Hydrazine, its derivatives and their salts
202. Octamoxin* and its salts
203. Warfarin* and its salts
204. Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
205. Methocarbamol*
206. Propatylnitrate*

207. 4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin
208. Fenadiazole*
209. Nitroxoline* and its salts
210. Hyoscyamine, its salts and derivatives
211. *Hyoscyamus niger L.* (leaves, seeds, powder and galenical preparations)
212. Pemoline* and its salts
213. Iodine
214. Decamethylenebis (trimethylammonium salts), e.g. decamethonium bromide*
215. Ipecacuanha (*Cephaelis ipecacuanha Brot.* and related species) (roots, powder and galenical preparations)
216. (2-Isopropylpent-4-enoyl)urea (apronalide)
217. α-Santonin(3S, 5aR, 9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-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 Sixth 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-Naphthylmethyl)-2-imidazoline
244. Naphazoline* and its salts
245. Neostigmine and its salts (e.g. neostigmine bromide*)
246. Nicotine and its salts
247. Amyl nitrites
248. Inorganic nitrites, with the exception of sodium nitrite

249. Nitrobenzene
250. Nitrocresols and their alkali metal salts
251. Nitrofurantoin*
252. Furazolidone*
253. Propane-1,2,3-triyl trinitrate
254. Acenocoumarol*
255. Alkali pentacyanonitrosylferrate (2-)
256. Nitrostilbenes, their homologues and their derivatives
257. Noradrenaline and its salts
258. Noscapine* and its salts
259. Guanethidine* and its salts
260. Oestrogens
261. Oleandrin
262. Chlortalidone*
263. Pelletierine and its salts
264. Pentachloroethane
265. Pentaerithrityl tetranitrate*
266. Petrichloral*
267. Octamylamine* and its salts
268. Picric acid
269. Phenacemide*
270. Difencloxazine*
271. 2-Phenylindane-1,3-dione (phenindione)
272. Ethylphenacemide*
273. Phenprocoumon*
274. Fenyramidol*
275. Triamterene* and its salts
276. 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. Butopiprine* 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 ()
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 (sulphanylamide and its derivatives obtained by substitution of one or more H-atoms of the $-NH_2$ groups) and their salts
308. Sultiame*
309. Neodymium and its salts
310. Thiotepa*
311. *Pilocarpus jaborandi Holmes* and its galenical preparations
312. Tellurium and its compounds
313. Xylometazoline and its salts
314. Tetrachloroethylene
315. Carbon tetrachloride
316. Hexaethyl tetraphosphate
317. Thallium and its compounds
318. *Thevetia neriifolia Juss.*, glycoside extract
319. Ethionamide*
320. Phenothiazine* and its compounds
321. Thiourea and its derivatives, with the exception of the one listed in the Third Schedule
322. Mephenesin* 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)

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[1]The presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment is permitted, provided that the radioactive substances are not enriched for the manufacture of cosmetic products and that their concentration falls within the limits set in the Directive laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations (OJ No 11, 20.2.1959, p.221/59).

327. Trichlormethine* and its salts
328. Tretamine*
329. Gallamine triethiodide*
330. *Urginea scilla Stern.* and its galenical preparations
331. Veratrine, its salts and galenical preparations
332. *Schoenocaulon officinale Lind.* (seeds and galenical preparations)
333. *Veratrum Spp.* and their preparations
334. Vinyl chloride monomer
335. Ergocalciferol* and cholecalciferol (vitamins D2 and D3)
336. Salts of O-alkyldithiocarbonic acids
337. Yohimbine and its salts
338. Dimethyl sulfoxide*
339. Diphenhydramine* and its salts
340. 4-tert-Butylphenol
341. 4-tert-Butylpyrocatechol
342. Dihydrotachysterol*
343. Dioxane
344. Morpholine and its salts
345. *Pyrethrum album L.* and its galenical preparations
346. 2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyldimethylamine
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 dihypoiodite
362. 3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronapthalen
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. Pyrithione sodium (INNM)
370. N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)
371. 2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)
372. 6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (minoxidil) and its salts.
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. Benzoyl peroxide
383. 2-Amino-4-nitrophenol
384. 2-Amino-5-nitrophenol
385. 11α-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 dialkanolamines
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. (a) the skull, including the brain and eyes, tonsils and spinal cord of:
    - bovine animals aged 12 months;
    - ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum;

    and ingredients derived therefrom;

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

    However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:
    - transesterification or hydrolysis at at least 200°C 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
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)

THIRD SCHEDULE

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.

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
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	(c) 3% (by mass/mass as boric acid)	(c) 1. Not to be used in products for children under	(c) 1. Not to be used for children under three years of age

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		waving products)		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)	2. Not to be used on peeling or irritated skin.
1b	Tetraborates	(d) 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	(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	(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	(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

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		removed after application	percentages calculated as thioglycollic acid	seek medical advice - Wear suitable gloves (a) and (c) only	children
2b	Thioglycollic acid esters	Hair waving or straightening products: - general use - professional use	- 8% ready for use, pH 6 to 9.5 - 11% ready for use, pH 6 to 9.5 The abovementioned percentages are calculated as thioglycollic acid	The directions for use drawn up in the 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

		Restrictions			
:rence mber	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
					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	
8	o and m-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of p-phenylenediamines [1]	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	6% calculated as free base		(a) Can cause an allergic reaction. Contains 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,	Oxidizing colouring	10% calculated as free		

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 mum level authorized for each of them does not exceed the value given in column d.

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
	other N-substituted derivatives and their salts[2]	agents for hair dyeing (a) general use (b) professional use	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[2]	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10% calculated as free base		(a) Can cause an allergic reaction. Contains diaminophenols. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains diaminophenols. Can cause an allergic

[2] These substances may be used singly or in combination provided that the sum of the ratios of the levels of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed the value given in column d.

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
					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_2O_2 (40 volumes) present or released (b) 4% of H_2O_2 present or released (c) 2% of H_2O_2 present or released (d) 0.1% of H_2O_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[3]
14	Hydroquinone[2]	(a) Oxidizing colouring agents for hair dyeing 1. general use	2%		(a) 1. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them.

[3] Only if the concentration exceeds 0.05%.

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		2. professional use			Contains hydroquinone. 2. For professional use only. Contains hydroquinone. Rinse eyes immediately if product comes into contact with them.
		(b) Agents for localized skin lightener	2 %		(b) Contains hydroquinone. Avoid contact with the eyes. Apply to small areas. If irritation develops discontinue use. Do not use on children under the age of 12.
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent	(a) 5% by weight[4]		(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children.
		(b) Hair straightener 1. general use	(b) 1. 2% by weight[4]		(b) 1. Contains alkali. Avoid contact with eyes. Can cause

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

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
					blindness. Keep out of reach of children.
		2. professional use	2. 4.5% by weight[4]		2. For professional use only. Avoid contact with eyes. Can cause blindness.
		(c) pH adjuster - depilatories	(c) up to pH 12.7		(c) Keep out of reach of children. Avoid contact with eyes.
		(d) Other uses as pH adjuster	(d) up to pH 11		
15b	Lithium hydroxide	(a) Hair straightener 1. General use	(a) 1. 2% by weight[4]		1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
		2. Professional use	2. 4.5% by weight[4]		2. For professional use only. Avoid contact with eyes. Can cause blindness
		(b) Other uses			

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
15c	Calcium hydroxide	(a) Hair straighteners containing 2 components: calcium hydroxide and a guanidine salt (b) Other uses	(a) 7% by weight of calcium hydroxide		Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
16	α-naphthol	Colouring agent for hair dyeing	0.5%		Contains α-naphthol
17	Sodium nitrite	Rust inhibitor	0.2%	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0.3%		
19	Phenol and its alkali salts	Soaps and shampoos	1% calculated as phenol		Contains phenol
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[5]	(a) Oxidizing colouring agent for	(a) 5 %		(a)

[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 the value given in column d.

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		hair dyeing 1. General use			1. Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them.
		2. Professional use			2. For professional use only. Contains resorcinol. Rinse eyes immediately if product comes into contact with them.
		(b) Hair lotions and shampoos	(b) 0.5%		(b) Contains resorcinol.
23	(a) Alkali sulphides	(a) Depilatories	(a) 2% calculated as sulphur, pH ≤ 12.7		(a) Keep out of reach of children. Avoid contact with eyes.
	(b) Alkaline earth sulphides	(b) Depilatories	(b) 6% calculated as sulphur, pH ≤ 12.7		(b) Keep out of reach of children. Avoid contact with eyes.
24	Water soluble zinc salts with the exception of		1% calculated as zinc		

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
	zinc 4-hydroxy-benzenesulphonate and zinc pyrithione				
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
33	Ammonium fluoride	ditto	0.15% ditto		Contains ammonium fluoride

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
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	Contains 1,3-Bis(hydroxymethyl)

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		(b) Hair care preparations	(b) up to 2%	(sprays) (b) The pH of the product as applied must be less than 4	imidazolidene-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavourings			
46	6-methylcoumarin	Oral hygiene products	0.003%		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this 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%		- Contains silver nitrate - Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Antidandruff shampoos	1%		- Contains selenium disulphide - Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and the	Antiperspirants	20% as anhydrous aluminium zirconium chloride hydroxide 5.4% as zirconium	1. The ratio of the number of Al atoms to that of Zr atoms must be	Do not apply to irritated or damaged skin

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
	aluminium zirconium chloride hydroxide glycine complexes			between 2 and 10 2. The ratio of the number of (Al+Zr) atoms to that of Cl atoms must be between 0.9 and 2.1 3. Prohibited in aerosol dispensers (sprays)	
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		
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	2%	As a preservative, see Sixth Schedule, No 43	

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

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
		(b) Shampoos and face care products	(b) 2.1% calculated as Sr. When mixed with other permitted Sr products, the total Sr content must not exceed 2.1%.		
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 dialkanolamides		Maximum dialkanolamine content: 0.5%	- Do not use with nitrosating systems - Maximum dialkanolamine content: 5% (concerns raw materials) - Maximum N-nitroso-dialkanolamine content: 50 µg/kg - Keep in nitrite-free containers	
61	Monoalklanol-amines		Maximum dialkanolamine content: 0.5%	- Do not use with nitrosating systems - Minimum purity: 99%	

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

		Restrictions			
Reference Number	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e	f
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
		(b) Other products	(b) 0.1% as benzalkonium chloride		(b) Avoid contact with the eyes

FOURTH SCHEDULE

List of Colouring Agents allowed for use in Cosmetic Products[6]

Field of application

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

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
10006	Green				x	
10020	Green			x		
10316[8]	Yellow		x			
11680	Yellow			x		
11710	Yellow			x		
11725	Orange				x	
11920	Orange	x				
12010	Red			x		
12085[8]	Red	x				3% maximum concentration in the finished product
12120	Red				x	

[6] 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.

[7] 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.

[8] 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.

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
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[8]	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[8]	Red	x				
15865[8]	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	

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
18690	Yellow				x	
18736	Red				x	
18820	Yellow				x	
18965	Yellow	x				
19140[8]	Yellow	x				E 102
20040	Yellow				x	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[8]	Red				x	
27755	Black	x				E 152
28440	Black	x				E 151
40215	Orange				x	
40800	Orange	x				
40820	Orange	x				E 160e
40825	Orange	x				E 160f
40850	Orange	x				E 161g
42045	Blue			x		
42051[8]	Blue	x				E 131
42053	Green	x				

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
42080	Blue				x	
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

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
45430[8]	Red	x				E 127, ditto
47000	Yellow			x		
47005	Yellow	x				E 104
50325	Violet				x	
50420	Black			x		
51319	Violet				x	
58000	Red	x				
59040	Green			x		
60724	Violet				x	
60725	Violet	x				
60730	Violet			x		
61565	Green	x				
61570	Green	x				
61585	Blue				x	
62045	Blue				x	
69800	Blue	x				E 130
69825	Blue	x				
71105	Orange			x		
73000	Blue	x				
73015	Blue	x				E 132
73360	Red	x				
73385	Violet	x				
73900	Violet				x	
73915	Red				x	
74100	Blue				x	
74160	Blue	x				
74180	Blue				x	
74260	Green		x			
75100	Yellow	x				
75120	Orange	x				E 160b
75125	Yellow	x				E 160d

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
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
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				

		Field of application				
Colour index number or denomination	Colour	1	2	3	4	Other limitations and requirements[7]
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
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 Substances Excluded from the Scope of the Order

1. [deleted]
2. [deleted]
3. [deleted]
4. [deleted]
5. Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in the Second Schedule, strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in the Third Schedule, and of strontium salts, lakes and pigments of the colouring agents listed with reference ([8]) in the Fourth Schedule.
6. [deleted]
7. [deleted]
8. [deleted].
9. [deleted]

SIXTH 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 ([6])
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	Pyrithione zinc (INN) (*)	0.5%	Authorized in products rinsed off Forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogen sulphites (*)	0.2% expressed as free SO_2		
10	Sodium iodate	0.1%	Rinse-off products only	
11	Chlorobutanol (INN)	0.5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters (*)	0.4% (acid) for 1 ester, 0.8% (acid) for mixtures of esters		

[6] 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
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'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		
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'-	

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
			Tetrachloroazoxybenzene < 1 ppm	
24	4-Chloro-m-cresol (*)	0.2%	Prohibited in products intended to come into contact with mucous membranes	
25	Tricolosan (INN) (*)	0.3%		
26	4-Chloro-3,5-xylenol (*)	0.5%		
27	3,3'-Bis (1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methylenediurea ("Imidazolidinyl urea") (*)	0.6%		
28	Poly (1-hexamethylenebiguanide hydrochloride) (*)	0.3%		
29	2-Phenoxyethanol (*)	1%		
30	Hexamethylenetetramine (*) (methenamine) (INN)	0.15%		
31	Methenamine 3-chloroallylochloride (INNM)	0.2%		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*)	0.5%		
33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (*)	0.6%		
34	Benzyl alcohol (*)	1%		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)-2-pyridone and its methanolamine salt (*)	1.0% 0.5%	Products rinsed off For other products	
36	1,2-Dibromo-2,4-dicyanobutane	0.1%	Not to be used in cosmetic sunscreen products at a	

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
			concentration exceeding 0.025%	
37	6,6-Dibromo-4,4-dichloro-2,2-methylenediphenol (Bromochlorophen) (*)	0.1%		
38	4-Isopropyl-m-cresol	0.1%		
39	Mixture of 5-Chloro-2-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	
44	Alkyl (C12-C22) trimethyl ammonium bromide and chloride (*)	0.1%		
45	4,4-dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0.5%		
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (*)	0.1%		

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)
49	5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane	0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
50	3-(p-chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
52	Silver chloride deposited on titanium dioxide	0.004% calculated as AgCl	20% AgCl (w/w) on TiO_2. Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips.	
53	Benzethonium chloride	0.1%	Rinse-off products only	
54	Benzalkonium chloride, bromide and saccharinate (+)	0.1% calculated as benzalkonium chloride	Not for oral hygiene and lip products	Avoid contact with the eyes
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	
56	3-Iodo-2-propynylbutylcarbamate	0.05%	1. Not to be used for oral hygiene and lipcare products 2. If the concentration in products intended to remain on the skin exceeds 0.02%	Contains iodine.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
			add the phrase: Contains iodine	

SEVENTH SCHEDULE

List of UV Filters which cosmetic products may contain

For the purposes of this Order, UV (ultraviolet) 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 (7)
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)		
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-Trianilino-(p-Carbo-2'-Ethylhexyl-1'-Oxy)-1,3,5-Triazine (Octyl Triazone)	5%		
16	Phenol, 2-(2H-Benzotriazol-2-yl)-4-methyl-6-	15%		

[7] 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
	(2-methyl-3-(1,3,3,3-tetra-methyl-1-(trimethylsilyl)oxy)-disilo-xanyl)propyl) (Drometrizole Trisiloxane)			
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%		

EIGHTH SCHEDULE

Symbol to be Used



NINTH 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