

COUNCIL DIRECTIVE

of 27 July 1976

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

(76/768/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

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

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

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

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

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

Whereas it is necessary to determine at Community level the regulations which must be observed as

regards the composition, labelling and packaging of cosmetic products;

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

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

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

Whereas, in particular, the determination of the methods of analysis together with possible modifications or additions which may have to be made to them on the basis of the results of scientific and technical research, are implementing measures of a technical nature; whereas it is advisable to entrust their adoption to the Commission, subject to certain conditions specified in this Directive, for the purpose of simplifying and accelerating the procedure;

Whereas technical progress necessitates rapid adaptation of the technical provisions defined in this Directive and in subsequent Directives in this field; whereas it is advisable, in order to facilitate implementation of the measures necessary for this purpose,

⁽¹⁾ OJ No C 40, 8. 4. 1974, p. 71.

⁽²⁾ OJ No C 60, 26. 7. 1973, p. 16.

to provide for a procedure establishing close co-operation between the Member States and the Commission within the Committee for adaptation to technical progress of Directives aimed at the removal of technical obstacles to trade in the cosmetic products sector;

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.

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

3. Cosmetic products containing one of the substances listed in Annex V and cosmetic products containing colouring agents other than those referred to in Annexes III and IV and which are not intended to come into contact with the mucous membranes are excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to these products.

Article 2

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

Article 3

Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.

Article 4

Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

- (a) substances listed in Annex II;
- (b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;
- (c) colouring agents other than those listed in the second part of Annex III, if these products are intended for application in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs;
- (d) colouring agents listed in the second part of Annex III, beyond the limits and outside the conditions laid down, if these products are intended for application in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs.

Article 5

For a period of three years from notification of this Directive, Member States shall accept the marketing of cosmetic products containing:

- (a) the substances listed in Part 1 of Annex IV within the limits and under the conditions laid down;
- (b) the colouring agents listed in Part 2 of Annex IV within the limits and under the conditions laid down, if these products are intended for application in the vicinity of the eyes, on the lips, in the oral cavity, or to the external genital organs;
- (c) the colouring agents listed in Part 3 of Annex IV, if these products either are not intended to come into contact with the mucous membranes or are only intended to come into brief contact with the skin.

On expiry of the three year period, these substances and colouring agents shall:

- either be definitively permitted,
- or definitively prohibited (Annex II),

- or retained for a further period of three years in Annex IV,
- or deleted from all Annexes to this Directive.

Article 6

1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if their packaging, containers or labels bear the following information in indelible, easily legible and visible lettering:
 - (a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who are established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community;
 - (b) the nominal content at the time of packaging;
 - (c) the expiry date for products with a stability of less than three years;
 - (d) particular precautions to be observed in use, and especially those listed in the column 'Conditions of use and warnings which must be printed on the label' in Annexes III and IV, and which must appear on the container; where this is impossible for practical reasons, this information must appear on the packaging or on an enclosed leaflet, but in the latter case an abbreviated external indication must appear on the container, referring the consumer to the information specified;
 - (e) the batch number of manufacture or the reference for identifying the goods; however, where this is impossible for practical reasons because the cosmetic articles are too small, such information need appear only on the multiple retail pack or sleeve of these articles.
2. Member States shall take all measures necessary to ensure that in the labelling, presentation for sale and advertising of cosmetic products, the wording, use of names, trade marks, images or other signs, figurative or otherwise, suggesting a characteristic which the products in question do not possess, shall be prohibited.

Article 7

1. Member States may not, for reasons related to the requirements laid down in this Directive and the

Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.

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

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

Article 8

1. In accordance with the procedure laid down in Article 10 the following shall be determined:
 - the methods of analysis necessary for checking the composition of cosmetic products,
 - the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.
2. The amendments necessary for adapting Annex II to technical progress shall be adopted in accordance with the same procedure.

Article 9

1. The Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector, hereinafter called 'the Committee', is hereby set up. It shall consist of representatives of the Member States with a representative of the Commission as chairman.
2. The Committee shall adopt its own rules of procedure.

Article 10

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman according to the urgency of the matter. Opinions shall be adopted by a majority of 41 votes, the votes of Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures when they are in accordance with the opinion of the Committee.

(b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

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

Article 12

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

2. The Commission shall, within six weeks, consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.

3. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

Article 13

Precise reasons shall be stated for any individual measures placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Directive. It shall be notified to the party concerned together with particulars of the remedies available to him under the laws in force in the Member States and of the time limits allowed for the exercise of such remedies.

Article 14

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

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

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

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 27 July 1976.

For the Council

The President

M. van der STOEL

ANNEX I

ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc.).
- Depilatories.
- Deodorants and anti-perspirants.
- Hair care products:
 - hair tints and bleaches,
 - products for waving, straightening and fixing,
 - setting products,
 - cleansing products (lotions, powders, shampoos),
 - conditioning products (lotions, creams, oils),
 - hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc.).
- Products for making up and removing make-up from the face and the eyes.
- Products intended for application to the lips.
- Products for care of the teeth and the mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.
- Anti-wrinkle products.

ANNEX II

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. β -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. Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe
22. Aniline, its salts and its halogenated and sulphonated derivatives
23. Betoxycaïne* and its salts
24. Zoxazolamine*
25. Procainamide*, its salts and derivatives
26. Benzidine
27. Tuaminoheptane*, its isomers and salts
28. Octodrine* and its salts
29. 2-Amino-1,2-bis (4-methoxyphenyl)ethanol and its salts
30. 1,3-dimethylpentylamine and its salts

(*) In this Directive, names followed by an asterisk are those published in 'Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN', WHO, Geneva, August 1975.

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, with the exception of that given in Annex IV
40. Antimony and its compounds
41. *Apocynum cannabinum* L. and its preparations
42. Apomorphine (5,6,6a 7-tetrahydro-6-methyl-4H-dibenzo [de, g]= quinoline-10,11-dihydric alcohol) and its salts
43. Arsenic and its compounds
44. *Atropa belladonna* L. and its preparations
45. Atropine, its salts and derivatives
46. Barium salts, with the exception of barium sulphate, lakes prepared from barium sulphate and pigments prepared from the colouring agents listed in Annex III, Part 2 and Annex IV, Parts 2 and 3 and marked Ba
47. Benzene
48. 4,5-Dihydrobenzimidazol-4-one
49. Benzazepines and benzadiazepines, their salts and derivatives
50. 1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts (amylocaine)
51. 2,2,6-Trimethyl-4-piperidyl benzoate and its salts (benzamine)
52. Isocarboxazide*
53. Bendroflumethiazide* and its derivatives
54. Beryllium and its compounds
55. Bromine, elemental
56. Breylium 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-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 galenical preparations
99. *Conium maculatum* L. (fruit, powder, galenical preparations)
100. Glycyclamide*
101. Cobalt benzenesulphonate
102. Colchicine, its salts and derivatives
103. Colchicoside and its derivatives
104. *Colchicum autumnale* L. and its galenical preparations
105. Convallatoxin
106. *Anamirta cocculus* L. (fruit)
107. *Croton tiglium* (oil)
108. 1-Butyl-3-(N-crotonoylsulphanilyl)urea
109. Curare and curarine
110. Synthetic curarizants
111. Hydrogen cyanide and its salts

112. 2- α -Cyclohexylbenzyl (N N N' N'-tetraethyl)trimethylenediamine (phenetamine)
113. Cyclomenol* and its salts
114. Sodium hexacyclonate*
115. Hexapropymate*
116. Dextropropoxyphene*
117. O O-Diacetyl-N-allyl-N-normorphine
118. Pipazetate* and its salts
119. 5-(α , β -dibromo-phenethyl)-5-methylhydantoin
120. N N-Pentamethylenebis (trimethylammonium salts), e.g. Pentamethonium bromide*
121. N N'-[Methylimino diethylene] bis (ethylidimethylammonium) 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. ambenonium 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. Tetrabenzazine* and its salts
140. Captodiame*
141. Mefeclozazine* and its salts
142. Dimethylamine
143. 1,1-Bis(dimethylaminomethyl) propyl benzoate and its salts (amydracaine, alypine)
144. Methapyrilene* and its salts
145. Metamfepramone* and its salts
146. Amitriptyline* and its salts
147. Metformin* and its salts
148. Isosorbide dinitrate*
149. Malononitrile
150. Succinonitrile
151. Dinitrophenol isomers
152. Inproquone*

153. Dimevamide* and its salts
154. Diphenylpyraline* and its salts
155. Sulfinpyrazone*
156. *N*-(3-Carbamoyl-3, 3-diphenylpropyl)-*N* *N*-diisopropylmethylammonium salts, e.g. isopropamide iodide*
157. Benactyzine*
158. Benzatropine* and its salts
159. Cyclizine* and its salts
160. 5,5-Diphenyl-4 imidazolidone
161. Probenecid*
162. Disulfiram*; thiram (ISO)
163. Emetine, its salts and derivatives
164. Ephedrine and its salts
165. Oxanamide* and its derivatives
166. Eserine or physostigmine and its salts
167. Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex IV, Part 1
168. Choline salts and their esters, e.g. choline chloride
169. Caramiphen* and its salts
170. Diethyl 4-nitrophenyl phosphate
171. Metethoheptazine* and its salts
172. Oxpheneridine* and its salts
173. Ethoheptazine* and its salts
174. Methheptazine* and its salts
175. Methylphenidate* and its salts
176. Doxylamine* and its salts
177. Tolboxane*
178. Monobenzone*
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 Annex IV, Part 1
192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*

193. Galantamine*
194. Progestogens, with the exception of those listed in Annex V
195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)
196. (1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethano-naphthalene (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-dimethano-naphthalene (isodrin-ISO)
199. Hydrastine, hydrastinine and their salts
200. Hydrazides and their salts
201. Hydrazine, its derivatives and their salts
202. Octamoxin* and its salts
203. Warfarin* and its salts
204. Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
205. Methocarbamol*
206. Propatynitrate*
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-trimethyl naphtho [1,2-b] furan-2,8-dione
218. *Lobelia inflata* L. and its galenical preparations
219. Lobeline* and its salts
220. Barbiturates
221. Mercury and its compounds, excluding the exceptions listed in Annex IV and Annex V
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-2*H*,5*H*-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. Nitroresols and their alkali metal salts
251. Nitrofurantoin*
252. Furazolidone*
253. Propane-1,2,3-triyl trinitrate
254. Acenocoumarol*
255. Alkali pentacyanonitrosylferrate (2-)
256. Nitrostilbenes, their homologues and their derivatives
257. Noradrenaline and its salts
258. Noscapine* and its salts
259. Guanethidine* and its salts
260. Oestrogens, with the exception of those listed in Annex V
261. Oleandrin
262. Chlortalidone*
263. Pelletierine and its salts
264. Pentachloroethane
265. Pentaerithrityl tetranitrate*
266. Petrichloral*
267. Octamylamine* and its salts
268. Pheno and its alkali salts, excluding the exceptions listed in Annex III
269. Phenacemide*
270. Difenclozazine*
271. 2-Phenylindane-1,3-dione (phenindione)
272. Ethylphenacemide*
273. Phenprocoumon*
274. Fenylramidol*

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 (Levophaceterane) 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 Annex V
290. Coniine
291. *Prunus laurocerasus* L. ('cherry laurel water')
292. Metyrapone*
293. Radioactive substances ⁽¹⁾
294. *Juniperus sabina* L. (leaves, essential oil and galenical preparations)
295. Hyoscine, its salts and derivatives
296. Gold salts
297. Selenium and its compounds
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 -NH₂ groups) and their salts
308. Sultiame*
309. Neodymium and its salts

⁽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).

310. Thiopepa*
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 those listed in Annex IV, Part 1
322. Mephesisin* and its esters
323. Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147, 9. 6. 1975, p. 13)
324. Tranylcypromine* and its salts
325. Trichloronitromethane (chloropicrine)
326. 2,2,2-Tribromoethanol (tribromoethyl alcohol)
327. Trichlormethine* and its salts
328. Tretamine*
329. Gallamine triethiodide*
330. *Urginea scilla* Stern. and its galenical preparations
331. Veratrine, its salts and galenical preparations
332. *Schoenocaulon officinale* Lind. (seeds and galenical preparations)
333. *Veratrum album* L. (roots and galenical 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, e.g. metabromsalan*, dibromsalan*
 352. Bithionol*
 353. Thiuram monosulphides
 354. Thiuram disulphides
 355. Dimethylformamide
 356. 4-Phenylbut-3-en-2-one
 357. Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used
 358. Furo [3,2-g] chromen-7-one and its alkyl-substituted derivatives (e.g. trioxysalan* and 8-methoxypsoralen), except for normal content in natural essences used
 359. Oil from the seeds of *Laurus nobilis* L.
 360. *Sassafras officinale* Nees oil containing safrole
 361. 5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypoidite
-

ANNEX III
PART 1
List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|--|---|---|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 1 | Boric acid | (a) Talcs (b) Products for oral hygiene (c) Other products | (a) 5% (b) 0.5% (c) 3% | (a) Not to be used in products for children under three years old | (a) Not to be used for babies |
| 2 | Mercaptoacetic acid and its salts and esters | (a) Hair waving or straightening products: — home use — professional use (b) Depilatories (c) Other hair care products which are removed after application | (a) — 8% ready for use pH ≤ 9.5 — 11% ready for use pH ≤ 9.5 (b) 5% pH ≤ 12.65 (c) 2% percentages calculated as mercaptoacetic acid | | |
| 3 | Oxalic acid, its esters and alkaline salts | Hair treatment products | 5% | | For hairdressers only |
| 4 | Chlorobutanol * | Preservative | 0.5% | Prohibited in aerosols | Contains chlorobutanol |
| 5 | Ammonia | | 6% calculated as NH ₃ | | Above 2% : Contains ammonia |

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|---|--|---|------------------------------------|--|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 6 | Tosylchloramide sodium * | | 0-2 % | | |
| 7 | Chlorates of the alkali metals | (a) Toothpaste (b) Other uses | (a) 5 % (b) 3 % | | |
| 8 | Dichloromethane | | 35 % (when mixed with 1, 1, 1-trichloroethane, total concentration must not exceed 35 %) | 0-2 % as maximum impurity content | For preparations in aerosol dispensers. Do not spray on a naked flame or any incandescent material |
| 9 | <i>o</i> and <i>m</i> -Phenylenediamines and their N-substituted derivatives and their salts; N-substituted derivatives of <i>p</i> -phenylenediamines ⁽¹⁾ | Oxidizing colouring agents for hair dyeing | 6 % calculated as free base | | Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows |
| 10 | Methylphenylenediamines, their N-substituted derivatives and their salts ⁽¹⁾ | Oxidizing colouring agents for hair dyeing | 10 % calculated as free base | | Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows |

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product at the maximum level authorized for each of them does not exceed 2.

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|-------------------------------|---|---|--|---|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 11 | Diaminophenols ⁽¹⁾ | Oxidizing colouring agents for hair dyeing | 10% calculated as free base | | Can cause an allergic reaction. Sensitivity test advisable before use Contains diaminophenols. Do not use to dye eyelashes or eyebrows |
| 12 | Dichlorophen * | | 0.5% maximum | | Contains dichlorophen* |
| 13 | Hydrogen peroxide | Oxidation colouring agents for hair dyeing | 40% volume, i.e. 12% H ₂ O ₂ | | Contains x% hydrogen peroxide |
| 14 | Formaldehyde | (a) Nail hardeners (b) Use as a preservative (c) For mouth hygiene products | (a) 5% (b) 0.2% (c) 0.1% calculated as formaldehyde | (b) Prohibited as a preservative in aerosol dispensers and in mouth hygiene products | (a) Protect cuticles with grease or oil. Contains x% formaldehyde (b) Contains formaldehyde |
| 15 | Hexachlorophene * | Preservative | 0.1% | Not to be used in products for children or personal hygiene products | Not to be used for babies. Contains hexachlorophene |
| 16 | Hydroquinone ⁽²⁾ | | 2% | | Do not use to dye eyelashes or eyebrows Rinse eyes immediately if product comes into contact with them Contains hydroquinone |

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product at the maximum level authorized for each of them does not exceed 1.

⁽²⁾ 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 at the maximum level authorized for each of them does not exceed 2.

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|-------------------------------|--|---|------------------------------------|--|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 17 | Potassium or sodium hydroxide | (a) Nail cuticle solvent (b) Hair straightener (c) Other uses as a neutralizer | (a) 5% by weight ⁽¹⁾ (b) 2% by weight ⁽¹⁾ (c) up to pH 11 | | (a) Avoid contact with eyes. Can cause blindness. Keep away from children (b) Avoid contact with eyes. Can cause blindness. Keep away from children |
| 18 | Lanolin | | | | Contains lanolin |
| 19 | α -Naphthol | Hair dye | 0.5% | | Contains α -naphthol |
| 20 | Sodium nitrite | Only as rust inhibitor | 0.2% | Do not use with secondary amines | |
| 21 | Nitromethane | Only as rust inhibitor | 0.3% | | |
| 22 | Phenol | Soaps and shampoos | 1% | | Contains phenol |
| 23 | Picric acid | Only as rust inhibitor | 1% | | Contains picric acid |
| 24 | Pyrogallol ⁽²⁾ | For dyeing hair only | 5% | | Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains pyrogallol |

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

⁽²⁾ These substances may be used singly or in combination provided that the sum of the ratios of the levels of the content of each of them in the cosmetic product at the maximum level authorized for each of them does not exceed 2.

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|---|---|--|------------------------------------|--|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 25 | Quinine and its salts | (a) Shampoos (b) Hair lotions | (a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base | | |
| 26 | Resorcinol ⁽¹⁾ | (a) Hair dyes (b) Hair lotions (c) Shampoos | (a) 5% (b) 0.5% (c) 0.5% | | (a) Can cause an allergic reaction. 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 (b) Can cause an allergic reaction. Contains resorcinol (c) Can cause an allergic reaction. Contains resorcinol. Rinse hair well after application |
| 27 | Ammonium sulphides, alkali and alkaline earth sulphides | | 2% in pastes 20% for monosulphides in aqueous solution without additive | | |
| 28 | Zinc (chloride and sulphate) | | 1% calculated as zinc | | |
| 29 | Zinc 4-hydroxybenzene-sulphonate | (a) Astringent (b) Deodorant | (a) 6% calculated as the anhydrous substance (b) 6% calculated as the anhydrous substance | | (a) Avoid contact with eyes (b) Do not spray into eyes |

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of the content of each of them in the cosmetic product at the maximum level authorized for each of them does not exceed 2.

PART 2

**LIST OF COLOURING AGENTS WHICH CAN BE CONTAINED IN COSMETICS
PRODUCTS INTENDED TO COME INTO CONTACT WITH THE MUCOUS
MEMBRANES ⁽¹⁾ ⁽²⁾ ⁽³⁾**

(a) Reds

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications ⁽⁴⁾ | Restrictions | | |
|------------------|------------------------------------|--|----------------------|----------------------------------|---|
| | | | Field of application | Maximum concentration authorized | Purity conditions ⁽⁴⁾ |
| 1 | 12 085 | | | 3% | |
| 2 | 12 150 | | | | |
| 3 | 12 490 | | | | |
| 4 | 14 720 | E 122 | | | E 122 |
| 5 | 14 815 | E 125 | | | E 125 |
| 6 | 15 525 | | | | |
| 7 | 15 580 | | | | |
| 8 | 15 585 | | r | | |
| 9 | 15 630 15 630(Ba) 15 630(Sr) | | | 3% | |
| 10 | 15 850 | E 180 | | | E 180 |
| 11 | 15 865 15 865(Sr) | | | | |
| 12 | 15 880 | | | | |
| 13 | 16 185 | E 123 | | | E 123 |
| 14 | 16 255 | E 124 | | | E 124 |
| 15 | 16 290 | E 126 | | | E 126 |
| 16 | 45 170 45 170(Ba) | | r | | |
| 17 | 45 370 | | | | Not more than 1% 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl) benzoic acid |
| 18 | 45 380 | | | | Ditto |
| 19 | 45 405 | | r | | Ditto |

⁽¹⁾ These colouring agents may also be used in cosmetics coming into contact with other parts of the body.

⁽²⁾ For certain colouring agents, restrictions are provided which may relate to the field of application of the colouring agent (the letter 'r' in the column of restrictions relating to the field of application signifies that the colouring agent is prohibited in the manufacture of cosmetic products which can come into contact with the mucous membranes of the eye, especially eye make-up and eye make-up removers) or to the maximum authorized concentration.

⁽³⁾ Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of the Directive are equally allowed.

⁽⁴⁾ Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directives of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives.

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications | Restrictions | | |
|------------------|---------------------|---|----------------------|----------------------------------|--|
| | | | Field of application | Maximum concentration authorized | Purity conditions |
| 20 | 45 410 | | | | Ditto |
| 21 | 45 425 | | | | 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 |
| 22 | 45 430 | E 127 | | | E 127 Ditto |
| 23 | 58 000 | | | | |
| 24 | 73 360 | | | | |
| 25 | 75 470 | E 120 | | | E 120 |
| 26 | 77 015 | E 420 | | | E 420 |
| 27 | 77 491 | E 172 | | | E 172 |
| 28 | | E 163 | | | E 163 |
| 29 | | E 162 | | | E 162 |

(b) Oranges and yellows

| | | | | | |
|----|--------|---------|---|----|---------|
| 1 | 10 316 | | r | | |
| 2 | 11 920 | | | | |
| 3 | 12 075 | | | | |
| 4 | 13 015 | E 105 | | | E 105 |
| 5 | 14 270 | E 103 | | | E 103 |
| 6 | 15 510 | | r | | |
| 7 | 15 980 | E 111 | | | E 111 |
| 8 | 15 985 | E 110 | | | E 110 |
| 9 | 19 140 | E 102 | | | E 102 |
| 10 | 45 350 | | | 6% | |
| 11 | 47 005 | E 104 | | | E 104 |
| 12 | 75 100 | | | | |
| 13 | 75 120 | E 160 b | | | E 160 b |
| 14 | 75 125 | E 160 d | | | E 160 d |

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications | Restrictions | | |
|------------------|---------------------|---|----------------------|---|-------------------|
| | | | Field of application | Maximum concentration authorized | Purity conditions |
| 15 | 75 130 | E 160 a | | | E 160 a |
| 16 | 75 135 | E 161 d | | | E 161 d |
| 17 | 75 300 | E 100 | | | E 100 |
| 18 | 77 489 | E 172 | | | E 172 |
| 19 | 77 492 | E 172 | | | E 172 |
| 20 | 40 820 | E 160 e | | | E 160 e |
| 21 | 40 825 | E 160 f | | | E 160 f |
| 22 | | E 101 | | | E 101 |
| 23 | 45 395 | | | When used in lipstick the colouring agent is admitted only in free acid form and in a maximum concentration of 1% | |
| 24 | | E 160 c | | | E 160 c |

(c) Greens and blues

| | | | | | |
|----|--------|-------|---|--|------------------------|
| 1 | 42 051 | E 131 | | | E 131 |
| 2 | 42 053 | | | | |
| 3 | 42 090 | | | | |
| 4 | 44 090 | | | | |
| 5 | 61 565 | | | | |
| 6 | 61 570 | | | | |
| 7 | 69 825 | | | | |
| 8 | 73 000 | | | | |
| 9 | 73 015 | E 132 | | | E 132 |
| 10 | 74 260 | | r | | |
| 11 | 75 810 | E 140 | | | E 140 |
| 12 | | E 141 | | | E 141 |
| 13 | 77 007 | | | | |
| 14 | 77 346 | | | | |
| 15 | 77 510 | | | | Free from cyanide ions |
| 16 | 69 800 | E 130 | | | E 130 |

(d) Violets, browns, blacks and whites

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications | Restrictions | | |
|---|---------------------|---|----------------------|----------------------------------|-------------------|
| | | | Field of application | Maximum concentration authorized | Purity conditions |
| 1 | 28 440 | E 151 | | | E 151 |
| 2 | 42 640 | | | | |
| 3 | 60 725 | | | | |
| 4 | 73 385 | | | | |
| 5 | 77 000 | E 173 | | | E 173 |
| 6 | 77 002 | | | | |
| 7 | 77 004 | | | | |
| 8 | 77 005 | | | | |
| 9 | 77 120 | | | | |
| 10 | 77 220 | E 170 | | | E 170 |
| 11 | 77 231 | | | | |
| 12 | 77 266 | Part of E 153 | | | E 153 |
| 13 | 77 267 | Part of E 153 | | | E 153 |
| 14 | 77 400 | | | | |
| 15 | 77 480 | E 175 | | | E 175 |
| 16 | 77 499 | E 172 | | | E 172 |
| 17 | 77 713 | | | | |
| 18 | 77 742 | | | | |
| 19 | 77 745 | | | | |
| 20 | 77 820 | E 174 | | | E 174 |
| 21 | 77 891 | E 171 Titanium dioxide (and its mixtures with mica) | | | E 171 |
| 22 | 77 947 | | | | |
| 23 | 75 170 | Guanine or pearl essence | | | |
| 24 (white 9) aluminium, zinc, magnesium and calcium stearates | | | | | |
| 25 | | E 150 Caramel | | | E 150 |

ANNEX IV

PART 1

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

| Reference number | Substance | Field of application and/or use | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|--|---|---|--|---|
| | | | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | | |
| a | b | c | d | e | f | |
| 1 | Methanol | Denaturant for ethanol and isopropyl alcohol | 5% Calculated as a % of ethanol and isopropyl alcohol | | | |
| 2 | Thiomersal* | Solely as a preservative in eye make-up | 0.007% Calculated as Hg. When mixed with other mercury compounds permitted under this Directive, total Hg concentration must not exceed 0.007% | | Contains thiomersal* | |
| 3 | Phenylmercuric compounds | Ditto | Ditto | | Contains phenylmercuric compounds | |
| 4 | Chloroform | Toothpaste | 4% | | | |
| 5 | 2,3-Dihydroxypropyl 4-aminobenzoate | | 5% | | Contains 2,3-dihydroxypropyl 4-aminobenzoate | |
| 6 | Quinolin-8-ol and bis(8-hydroxyquinolinium) sulphate | | 0.3% in base | Not to be used in products applied after sunbathing. Not to be used in talcum powder for babies | Not to be used for babies | |

| Reference number | Substance | Restrictions | | | Conditions of use and warning 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 |
| 7 | Ammonium monofluorophosphate | Oral hygiene products | 0-15% Calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0-15% | | Contains ammonium monofluorophosphate |
| 8 | Sodium monofluorophosphate | Ditto | 0-15% Ditto | | Contains sodium monofluorophosphate |
| 9 | Potassium monofluorophosphate | Ditto | 0-15% Ditto | | Contains potassium monofluorophosphate |
| 10 | Calcium monofluorophosphate | Ditto | 0-15% Ditto | | Contains calcium monofluorophosphate |
| 11 | Calcium fluoride | Ditto | 0-15% Ditto | | Contains calcium fluoride |
| 12 | Sodium fluoride | Ditto | 0-15% Ditto | | Contains sodium fluoride |
| 13 | Potassium fluoride | Ditto | 0-15% Ditto | | Contains potassium fluoride |
| 14 | Ammonium fluoride | Ditto | 0-15% Ditto | | Contains ammonium fluoride |
| 15 | Aluminium fluoride | Ditto | 0-15% Ditto | | Contains aluminium fluoride |
| 16 | Stannous fluoride | Ditto | 0-15% Ditto | | Contains stannous fluoride |

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|---|---------------------------------|---|---|---|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 17 | Hexadecyl-trimethyl-ammonium fluoride | Ditto | 0-15 % Ditto | | Contains hexadecyl-trimethyl-ammonium fluoride |
| 18 | 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis ammonium difluoride | Ditto | 0-15 % Ditto | | Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride |
| 19 | NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride | Ditto | 0-15 % Ditto | | Contains NN'N'-tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride |
| 20 | Octadecyl-ammonium fluoride | Ditto | 0-15 % Ditto | | Contains octadecyl-ammonium fluoride |
| 21 | Sodium fluorosilicate | Ditto | 0-15 % Ditto | | Contains sodium fluorosilicate |
| 22 | Potassium fluorosilicate | Ditto | 0-15 % Ditto | | Contains potassium fluorosilicate |
| 23 | Ammonium fluorosilicate | Ditto | 0-15 % Ditto | | Contains ammonium fluorosilicate |
| 24 | Magnesium fluorosilicate | Ditto | 0-15 % Ditto | | Contains magnesium fluorosilicate |
| 25 | Safrole | | 100 ppm | | |
| 26 | 1,3-Bis(hydroxymethyl)imidazolidine-2-thione | Hair-care preparations | (a) Up to 2 % (b) From 2 to 8 % | (a) Prohibited in aerosol dispensers (b) Ditto | (a) Contains 1,3-bis(hydroxymethyl)imidazolidine-2-thione (b) — Rinse hair thoroughly after use — Contains 1,3-bis(hydroxymethyl)imidazolidine-2-thione |

| Reference number | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|------------------|--|---------------------------------|---|------------------------------------|---|
| | | Field of application and/or use | Maximum authorized concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 27 | 1,3-Bis (hydroxymethyl)-3-thiourea | Ditto | 6 % | Ditto | — Rinse hair thoroughly after use — Contains 1,3-bis(hydroxymethyl)-2-thiourea |
| 28 | Hydroxymethyl-2-thiourea | Ditto | 6 % | Ditto | — Rinse hair thoroughly after use — Contains hydroxymethyl-2-thiourea |
| 29 | 1-Hydroxymethylimidazolidine-2-thione | Ditto | 6 % | Ditto | — Rinse hair thoroughly after use — Contains 1-hydroxymethylimidazolidine-2-thione |
| 30 | 1-Monomorpholinomethyl-2-thiourea | Ditto | 6 % | Ditto | — Rinse thoroughly after use — Contains 1-morpholinomethyl-2-thiourea |
| 31 | 1,3 Bis(morpholinomethyl)-2-thiourea | Ditto | 6 % | Ditto | — Rinse hair thoroughly after use — Contains 1,3 bis(morpholinomethyl)-2-thiourea |
| 32 | 1,1,1-Trichloroethane (methyl chloroform) | Solvent for aerosol dispensers | 3,5 % When mixed with dichloromethane, total concentration must not exceed 3,5 % | | Do not spray on a naked flame or any incandescent material |
| 33 | Tribromosalicylanilides (e.g. tribromosalan [®]) | Soap | 1 % | | Contains tribromosalicylanilides |

PART 2

LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED WHICH MAY BE CONTAINED IN COSMETIC PRODUCTS INTENDED TO COME INTO CONTACT WITH THE MUCOUS MEMBRANES IN ACCORDANCE WITH ARTICLE 5 ⁽¹⁾ ⁽²⁾ ⁽³⁾

(a) **Reds**

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications ⁽⁴⁾ | Restrictions | | |
|------------------|----------------------|--|--|----------------------------------|----------------------------------|
| | | | Field of application | Maximum concentration authorized | Purity conditions ⁽⁴⁾ |
| 1 | 12 120 | | | | |
| 2 | 12 350 | | | | |
| 3 | 12 385 | | | | |
| 4 | 14 700 | | r | | |
| 5 | 15 500 15 500(Ba) | | Use of Basalts prohibited in lipsticks | | |
| 6 | 15 585(Ba) | | | | |
| 7 | 15 620 | | | | |
| 8 | 15 800 | | | | |
| 9 | 16 035 | | | | |
| 10 | 26 100 | | | | |
| 11 | 27 290 | | | | |
| 12 | 45 160 | | | | |
| 13 | 75 480 | | | | |
| 14 | 75 580 | | | | |

(b) **Oranges and yellows**

| | | | | | |
|---|--------|--|---|--|--|
| 1 | 18 965 | | | | |
| 2 | 45 340 | | | | |
| 3 | 47 000 | | r | | |

⁽¹⁾ These colouring agents may also be used in cosmetics coming into contact with other parts of the body.

⁽²⁾ For certain colouring agents, restrictions are provided which may relate to the field of application of the colouring agent (the letter 'r' in the column of restrictions relating to the field of application signifies that the colouring agent is prohibited in the manufacture of cosmetic products which can come into contact with the mucous membranes of the eye, especially eye make-up and eye make-up removers) or to the maximum authorized concentration.

⁽³⁾ Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of the Directive are equally allowed.

⁽⁴⁾ Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directives of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives.

(c) Greens and blues

| Reference number | Colour index number | Colouring agent number according to the EEC Directives of 1962 concerning food colouring matters or other indications | Restrictions | | |
|------------------|---------------------|---|----------------------|----------------------------------|-------------------------|
| | | | Field of application | Maximum concentration authorized | Purity conditions |
| 1 | 42 040 | | | | |
| 2 | 42 140 | | | | |
| 3 | 42 170 | | | | |
| 4 | 42 735 | | | | |
| 5 | 44 040 | | | | |
| 6 | 44 045 | | | | |
| 7 | 59 040 | | | | |
| 8 | 61 554 | | | | |
| 9 | 62 085 | | | | |
| 10 | 77 288 | | | | Free from chromate ions |
| 11 | 77 289 | | | | Ditto |
| 12 | 77 520 | | | | |
| 13 | 74 160 | | | | |

(d) Violets, browns, blacks and whites

| | | | | | |
|---|--------|--|--|--|-------|
| 1 | 20 170 | | | | |
| 2 | 27 755 | E 152 | | | E 152 |
| 3 | 42 580 | | | | |
| 4 | 45 190 | | | | |
| 5 | 77 019 | | | | |
| 6 | 77 163 | Bismuth chloride oxide (and its mixtures with mica) | | | |
| 7 | 77 265 | | | | |
| 8 | 77 718 | | | | |

PART 3

(A) LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR COSMETIC PRODUCTS WHICH DO NOT COME INTO CONTACT WITH THE MUCOUS MEMBRANES

Reds

12310, 12335, 12420, 12430, 12440, 16140, 16155, 16250, 17200, 18000, 18050, 18055, 18065, 26105, 45100, 50240, E121

Oranges and yellows

11680, 11710, 13065, 15575, 16230, 18690, 18736, 18745, 19120, 19130, 21230, 71105

Blues and greens

10006, 10020, 42045, 42050, 42080, 42755, 44025, 62095, 62550, 63000, 71255, 74100, 74220, 74350, *aa*-bis(5-bromo-4-hydroxy-6-methyl-*m*-cumenyl)toluene-2, α -sultone, *aa*bis(3,5-dibromo-4-hydroxy-*o*-tolyl)toluene-2, α -sultone, 1,4-bis(butylamino)anthraquinone

Violets, browns, blacks and whites

12010, 12196, 12480, 16580, 27905, 42555, 42571, 43625, 46500, 51319, 61710, 61800, sodium 2,4-diamino-azobenzenesulphonate and five related colouring agents (Brown FK), α -(5-bromo-6-hydroxy-*m*-tolyl)- α -(3-bromo-5-methyl-4-oxocyclohexa-2,5-dienylidene)toluene-2-sulphonic acid

(B) LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR COSMETIC PRODUCTS WHICH COME INTO CONTACT ONLY BRIEFLY WITH THE SKIN

Reds

11210, 12090, 12155, 12170, 12315, 12370, 12459, 12460, 13020, 14895, 14905, 16045, 16180, 18125, 18130, 24790, 27300, 27306, 28160, 45220, 60505, 60710, 62015, 73300

Yellows and oranges

11720, 11725, 11730, 11765, 11850, 11855, 11860, 11870, 12055, 12140, 12700, 12740, 12770, 12790, 13900, 14600, 15970, 15975, 18820, 18900, 19555, 21090, 21096, 21100, 21108, 21110, 21115, 22910, 25135, 25220, 26090, 29020, 40215, 40640, 41000, 45376, 47035, 48040, 48055, 56205, 4-(3-chlorophenylazo)-3-hydroxy-2 naphth-0-anisidide, trisodium 3-hydroxypyren-5,8,10-trisulphonate

Blues and greens

10025, 26360, 42052, 42085, 42095, 42100, 50315, 50320, 50400, 50405, 51175, 52015, 52020, 52030, 61505, 61585, 62045, 62100, 62105, 62125, 62130, 62500, 62560, 63010, 64500, 74180

Violets, browns, blacks and whites

12145, 14805, 15685, 17580, 20285, 20470, 21010, 25410, 30045, 30235, 40625, 42510, 42520, 42525, 42535, 42650, 48013, 57020, 60730, 61100, 61105, 61705, 62030, 63165, 63615

ANNEX V

LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THE DIRECTIVE

1. Lead acetate (for use in hair treatment products only).
 2. Hexachlorophene* (for all uses other than that stated in Part 1 of Annex III).
 3. Hormones
 - (a) — oestrone,
— oestradiol and its esters,
— oestriol and its esters;
 - (b) — progesterone,
— Ethisterone*.
 4. p-Phenylenediamine and its salts.
 5. Strontium and its salts, with the exception of those used in the colouring agents listed in Part 2 of Annex III and Parts 2 and 3 of Annex IV.
 6. Zirconium and its derivatives.
 7. Thiomersal* and phenylmercuric compounds (for use as preservatives in concentrated shampoos and creams containing non-ionic emulsifiers which render other preservatives ineffective; maximum concentration 0.003% calculated as Hg).
 8. Lidocaine*.
 9. Tyrothricin*.
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