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of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC) (repealed)

ANNEX I U.K.

П	I	1	UST:	\mathbf{R}	ΔТ	IV	\mathbf{F}	T	TZI	RV	, ($^{T}\DeltaT$	FG	OR	V	$\cap F$	C	\cap 9	15	\mathbf{AE}^{\prime}	$\Gamma I C$	7	p_{R}	(Γ	TI	C	ΓS
11	л	_ '	USI.	I\/	-7.1	1 1	Ŀ.	ட	101	\mathbf{D} 1	٠,	-AI	ĽU	o	1,	OI.	\cdot	O.	DΙΝ	IL.	11/	_ 1	[IN	J	ı	v	v.	IJ

	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.

ANNEX II U.K.

[FILIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS]

Textual Amendments

- F1 Inserted by Council Directive of 17 May 1982 (82/368/EEC).
- 1. N-5-Chlorobenzoxazol-2-ylacetamide

Skin-whitening products. Anti-wrinkle products.

- 2. [F12-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts]
- 3. Deanol aceglumate⁽¹⁾
- 4. Spironolactone*

- 5. [F1[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. [F12-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. [F1Imperatorin (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 Substances with androgenic effect 37. 38. Anthracene oil 39. Antibiotics [F2] 40. Antimony and its compounds 41. Apocynum cannabinum L. and its preparations 42. [F1Apomorphine (R 5,6,6a, 7-tetrahydro-6-methyl-4*H*-dibenzo [de,g]quinoline-10,11diol) and its salts 43. Arsenic and its compounds 44. Atropa belladonna L. and its preparations 45. Atropine, its salts and derivatives 46. [F3Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, and lakes, salts and pigments prepared from the colouring agents listed with the reference (5) in Annex III, Part 2 and Annex IV, Part 2.1 47. Benzene 48. [F1Benzimidazol-2(3*H*)-one] 49. [F1Benzazepines and benzodiazepines] [F11-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts] 50. 51. [F12,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts] 52. [F1 Isocarboxazid*] Bendroflumethiazide* and its derivatives 53. 54. Beryllium and its compounds 55. Bromine, elemental 56. Bretylium tosilate*
- 60. Benzilonium bromide*

Carbromal*

Bromisoval*

61. Tetrylammonium bromide*

Brompheniramine* and its salts

62. Brucine

57.

58.

59.

63. Tetracaine* and its salts

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- 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. [F1Nitroderivatives of carbazole]
- 73. Carbon disulphide
- 74. Catalase
- 75. Cephaeline and its salts
- 76. Chenopodium ambrosioides (essential oil)
- 77. 2,2,2-Trichloroethane-1,1-diol
- 78. Chlorine
- 79. Chlorpropamide*
- 80. [F1Diphenoxylate* hydrochloride]
- 81. 4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
- 82. Chlorzoxazone*
- 83. 2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)
- 84. Chlorprothixene* and its salts
- 85. Clofenamide*
- 86. $\int_{-\infty}^{F_I} N_i N$ -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. [F1Chlormezanone*]
- 92. Triparanol*
- 93. 2-[2(4-Chiorophenyl)-2-phenylacetyl] indane-1,3-dione (chlorophacinone-ISO)
- 94. Chlorphenoxamine*

- 95. [F12-[2-(4-Chlorophenyl)-2-phenylacetyl]indan 1,3-dione (chlorophacinone ISO)]
- 96. Chloroethane
- 97. Chromium; chromic acid and its salts
- 98. *Claviceps purpurea Tul.*, its alkaloids and galenical preparations
- 99. *Conium maculatum L.* (fruit, powder, galenical preparations)
- 100. Glycyclamide*
- 101. Cobalt benzenesulphonate
- 102. Colchicine, its salts and derivatives
- 103. Colchicoside and its derivatives
- 104. Golchicum autumnale L. and its galenical preparations
- 105. Convallatoxin
- 106. Anamirta cocculus L. (fruit)
- 107. Croton tiglium (oil)
- 108. 1-Butyl-3-(*N*-crotonoylsulphanilyl)urea
- 109. Curare and curarine
- 110. Synthetic curarizants
- 111. Hydrogen cyanide and its salts
- 112. $[^{F1}2-\alpha$ -Cyclohexylbenzyl(N,N,N',N',-tetraethyl)trimethylenediamine (phenetamine)]
- 113. Cyclomenol* and its salts
- 114. Sodium hexacyclonate*
- 115. Hexapropymate*
- 116. Dextropropoxyphene*
- 117. /^{F1}O, O'-Diacetyl-N-allyl-N-normorphine]
- 118. Pipazetate* and its salts
- 119. f^{FI} 5-($\alpha\beta$ -Dibromophenethyl)-5-methylhydantoin
- 120. *[FIN,N'*-Pentamethylenebis (trimethylammonium salts), e.g. pentamethonium bromide*]
- 121. *[FIN,N'-*[(Methylimino)diethylene]bis(ethyldimethylammonium) salts, e.g. azamethonium bromide*]
- 122. Cyclarbamate*
- 123. Clofenotane*; DDT (ISO)
- 124. *[FIN,N'*-Hexamethylenebis(trimethylammonium) salts, e.g. hexamethonium bromide*]

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- 125. Dichloroethanes (ethylene chlorides)
- 126. Dichloroethylenes (acetylene chlorides)
- Lysergide* and its salts 127.
- 128. [F12-Diethylaminoethyl-3-hydroxy-4-phenylbenzoate and its salts]
- Cinchocaine* and its salts 129.
- 130. 3-Diethylaminopropyl cinnamate
- 131. f^{F1}O,O'-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)]
- 132. [F1 [Oxalylbisiminoethylene)]bis[(o-chlorobenzyl)diethylammonium salts], e.g. ambenomium cloride*1
- 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. [F11,1-Bis(dimethylaminomethyl)propyl benzoate (amydricaine, alypine) and its salts]
- Methapyrilene* and its salts 144.
- 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. [F1N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethyl-ammonium salts, e.g. isopropamide iodide*]
- 157. Benactyzine*
- 158. Benzatropine* and its salts
- 159. Cyclizine* and its salts
- 160. [F15,5-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 [F4Annex 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. [F5[X14-Benzyloxyphenol 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*

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- 186. Paramethasone*
- 187. Fluanisone*
- 188. Trifluperidol*
- 189. Fluoresone*
- 190. Fluorouracil*
- 191. [F1Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1]
- 192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*
- 193. Galantamine*
- 194. Progestogens [F2]
- 195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)
- 196. [F1(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8aoctahydro-1,4:5,8-dimethano-naphthalene (endrin-ISO)]
- 197. Hexachloroethane
- (1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-198. 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. [F1Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid]
- 205. Methocarbamol*
- 206. Propatylnitrate*
- 207. [F14,4'-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. [F1Decamethylenebis(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. [$^{\text{F1}}\alpha$ -Santonin [(3S,5a*R*,9b*S*)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto [1,2-b] furan-2,8-dione]]
- 218. Lobelia inflata L. and its galenical preparations
- 219. Lobeline* and its salts
- 220. Barbiturates
- [F6]Mercury and its compounds, except those special cases included [F7 in Annex VI, Part 1]
- 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. [F13,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,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. [F13-(1-Naphthyl)-4-hydroxycoumarin]

244. Naphazoline* and its salts 245. Neostigmine and its salts (e.g. neostigmine bromide*) 246. Nicotine and its salts 247. Amyl nitrites 248. Inorganic nitrites, with the exception of sodium nitrite 249. Nitrobenzene 250. Nitrocresols and their alkali metal salts 251. Nitrofurantoin* 252. Furazolidone* 253. Propane-1,2,3-triyl trinitrate 254. Acenocoumarol* 255. Alkali pentacyanonitrosylferrate (2-) 256. Nitrostilbenes, their homologues and their derivatives 257. Noradrenaline and its salts 258. Noscapine* and its salts 159. Guanethidine* and its salts 260. Oestrogens [F8] 261. Oleandrin 262. Chlortalidone* 263. Pelletierine and its salts 264. Pentachloroethane 265. Pentaerithrityl tetranitrate* 266. Petrichloral* 267. Octamylamine* and its salts 268. [F1Picric acid] 269. Phenacemide* 270. Difendoxazine* [F12-Phenylindan-1,3-dione (phenindione)] 271. 272. Ethylphenacemide* 273. Phenprocoumon*

274.

275.

Fenyramidol*

Triamterene* and its salts

302.

303.

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276. [F1Tetraethyl pyrophosphate; TEPP (ISO)] 277. Tritolyl phosphate 278. Psilocybine* 279. Phosphorus and metal phosphides 280. Thalidomide* and its salts 281. Physostigma venenosum Balf. 282. Picrotoxin 283. Pilocarpine and its salts 284. [^{F1}α-Piperidin-2-ylbenzyl acette (SIC! laevorotatory threoform acetate) (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 I^{F9}compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated 290. Coniine 291. Prunus laurocerasus L. ('cherry laurel water') 292. Metyrapone* 293. [F10]Radioactive substances, as defined by Directive 96/29/Euratom⁽²⁾ laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.] 294. Juniperus sabina L. (leaves, essential oil and galenical preparations) 295. Hyoscine, its salts and derivatives 296. Gold salts 297. [^{F4}Selenium and its compounds with the exception of selenium disulphiele under the conditions set out under reference No 49 in Annex Ill, Part 1] 298. Solanum nigrum L. and its galenical preparations 299. Sparteine and its salts 300. Glucocorticoids 301. Datura stramonium L. and its galenical preparations

Strophantines, their aglucones and their respective derivatives

Strophantus species and their galenical preparations

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- 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. [F1Sulphonamides (sulphanilamide and its derivatives...) and their salts obtained by substitution of one or more H-atoms of the -NH₂ groups) and their salts
- 308. Sultiame*
- 309. Neodymium and its salts
- 310. Thiotepa*
- 311. Pilocarpus jaborandi Holmes and its galenical preparations
- 312. Tellurium and its compounds
- 313. [F1Xylometazoline* 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. [FIThiourea and its derivatives, with the exception of the one listed in Annex III, Part 1]
- 322. Mephenesin* and its esters
- 323. Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147, 9. 6. 1975, p. 13)
- 324. Tranyleypromine* and its salts
- 325. Trichloronitromethane (chloropicrine)
- 326. 2,2,2-Tribromoethanol (tribromoethyl alcohol)
- 327. Trichiormethine* and its salts
- 328. Tretamine*
- 329. Gallamine triethiodide*
- 330. Urginea scilla Stern. and its galenical preparations
- 331. Veratrine, its salts and galenical preparations
- 332. Schoenocaulon officinale Lind. (seeds and galenical preparations)

360.

concentration does not exceed:

100 ppm in the finished product,

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333.	[F11 Veratrum Spp. and their preparations]
334.	Vinyl chloride monomer
335.	Ergocalciferol* and cholecalciferol (vitamins D ₂ and D ₃)
336.	Salts of O-alkyldithiocarbonic acids
337.	Yobimbine and its salts
338.	Dimethyl sulfoxide*
339.	Diphenhydramine* and its salts
340.	4-tert-Butylphenol
341.	4-tert-Butylpyrocatechol
342.	Dihydrotachysterol
343.	Dioxane
344.	Morpholine and its salts
345.	Pyretbrum album L. and its galenical preparations
346.	[F12-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyldimethylamine maleate]
347.	Tripelennamine*
348.	Tetrachlorosalicylanilides
349.	Dichlorosalicylanilides
350.	[F1Tetrabromosalicylanilides [F12]
351.	Dibromosalicylanilides][F12]
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.	[F13Furocoumarines (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 <i>Laurus nobilis L</i> .

[F1Safrole except for normal content in the natural essences used and provided the

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. [^{F14}.....]
- 362. [F153'-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-tetrahydronaphtalen]
- 363. $\int_{0}^{F_{16}}O$ -phenylenediamine and its salts
- 364. 4-methyl-*m*-phenylenediamine and its salts.]
- 365. $[^{F14}, \dots]$
- 365. [F15 Aristolochic acid and its salts; *Aristolochia* spp. and their preparations]
- 366. | F¹⁷Chloroform
- 367. $[^{F14}, \dots]$
- 367. [F152,3,7,8-Tetra chlorodibenzo-p-dioxin]
- 368. 2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)
- 369. Pyrithione sodium (INNM)]
- 370. \(\int_F^{F18} \) N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (captan)
- 371. 2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (hexachlorophene)]
- 372. $[^{F14}....]$
- 373. $[^{F14}$
- 374.]
- 372. [F19]F156-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide (minoxidil) and its salts
- 373. 3,4',5-Tribromosalicylanilide
- 374. *Phytolacca* spp. and their preparations
- 375. Tretinoin (retinoic acid and its salts)
- 376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole CI 76050) [F9 and their salts]
- 377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) [F9 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]

403.

Strontium nitrate

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381.
         [F20] Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
         \begin{bmatrix} F21 & \dots \end{bmatrix}
382.
383.
         2-Amino.4-nitrophenol
384.
         2-Amino-5-nitrophenol]
385.
         [<sup>F9</sup>11 α-Hydroxypregn-4-ene-3,20-dione and its esters
385.
         [F1511α-Hydroxypregn-4-ene-3, 20-dione) and its esters]
         \Gamma^{F14}....]
386.
386.
         [F15Colouring agent C.I. 42 640]
387.
         Colouring agent CI 13 065
388.
         Colouring agent CI 42 535
389.
         Colouring agent CI 61 5541
390.
         [F14.....
391.
         . . . . .
392.
393.
         . . . . .
394.
         . . . . .]
390.
         [F15Anti-androgens of steroidal structure
         Zirconium and its compounds, with the exception of the substances listed under
391.
         reference number 50 in Annex III, Part One, and the zirconium lakes, pigments or salts
         of the colouring agents listed in Annex IV, Part One, with reference number 3
393.
         Acetonitrile
394.
         Tetrahydrozoline and its salts]
395.
         I<sup>F7</sup>Hvdroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in
         Annex III, Part 1
         Dithio-2,2-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) -
396.
         (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.
         [F221,2-epoxybutane
401.
         Colouring agent CI 15585
402.
          Strontium lactate
```

- 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. [F5Secondary alkyl- and alkanolamines and their salts]]
- 412. [F234-Amino-2-nitrophenol]
- 413. [F242-Methyl-m-phenylenediamine]
- 414. [F134-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)]
- $427 \qquad [^{F25}....]$
- 416. [F13Cells, tissues or products of human origin
- 417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein*)]
- 418. [F263-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)]
- [F27] F28 From the date referred to in Article 22(1) of Regulation (EC) No 999/2001 of the European Parliament and of the Council (3), the specified risk materials as designated in Annex V to that Regulation, and ingredients derived therefrom.

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

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

- [F29] 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 (2 000 hPa) for eight minutes or equivalent conditions.]
- 420. [F30 Crude and refined coal tars]
- 421. [F311,1,3,3,5,-Pentamethyl-4,6-dinitroindane (moskene)
- 422. 5-*tert*-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene).]
- 423. [F32Alanroot oil (*Inula helenium*) (CAS No 97676-35-2), when used as a fragrance ingredient.

- 424. Benzyl cyanide (CAS No 140-29-4), when used as a fragrance ingredient.
- 425. Cyclamen alcohol (CAS No 4756-19-8), when used as a fragrance ingredient.
- 426. Diethyl maleate (CAS No 141-05-9), when used as a fragrance ingredient.
- 427. Dihydrocoumarine (CAS No 119-84-6), when used as a fragrance ingredient.
- 428. 2,4-Dihydroxy-3-methylbenzaldehyde (CAS No 6248-20-0), when used as a fragrance ingredient.
- 429. 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No 40607-48-5), when used as a fragrance ingredient.
- 430. 4,6-Dimethyl-8-*tert*-butylcoumarin (CAS No 17874-34-9), when used as a fragrance ingredient.
- 431. Dimethyl citraconate (CAS No 617-54-9), when used as a fragrance ingredient.
- 432. 7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No 26651-96-7), when used as a fragrance ingredient.
- 433. 6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No 141-10-6), when used as a fragrance ingredient.
- 434. Diphenylamine (CAS No 122-39-4), when used as a fragrance ingredient.
- 435. Ethyl acrylate (CAS No 140-88-5), when used as a fragrance ingredient.
- 436. Fig leaf absolute (*Ficus carica*) (CAS No 68916-52-9), when used as a fragrance ingredient.
- 437. *trans*-2-Heptenal (CAS No 18829-55-5), when used as a fragrance ingredient.
- 438. *trans-2-*Hexenal diethyl acetal (CAS No 67746-30-9), when used as a fragrance ingredient.
- 439. *trans*-2-Hexenal dimethyl acetal (CAS No 18318-83-7), when used as a fragrance ingredient.
- 440. Hydroabietyl alcohol (CAS No 13393-93-6), when used as a fragrance ingredient.
- 441. 6-Isopropyl-2-decahydronaphthalenol (CAS No 34131-99-2), when used as a fragrance ingredient.
- 7-Methoxycoumarin (CAS No 531-59-9), when used as a fragrance ingredient.
- 443. 4-(4-Methoxyphenyl)-3-butene-2-one (CAS No 943-88-4), when used as a fragrance ingredient.
- 1-(4-Methoxyphenyl)-1-penten-3-one (CAS No 104-27-8), when used as a fragrance ingredient.
- 445. Methyl trans-2-butenoate (CAS No 623-43-8), when used as a fragrance ingredient.
- 446. 7-Methylcoumarin (CAS No 2445-83-2), when used as a fragrance ingredient.
- 5-Methyl-2,3-hexanedione (CAS No 13706-86-0), when used as a fragrance ingredient.

- 448. 2-Pentylidenecyclohexanone (CAS No 25677-40-1), when used as a fragrance ingredient.
- 3,6,10-Trimethyl-3,5,9-undecatrien-2-one (CAS No 1117-41-5), when used as a fragrance ingredient.
- 450. Verbena oil (*Lippia citriodora* Kunth.) (CAS No 8024-12-2), when used as a fragrance ingredient.
- 451. [X2]Methyleugenol (CAS No 93-15-2)] except for normal content in the natural essences used and provided that the concentration does not exceed:
 - (a) 0,01 % in fine fragrance
 - (b) 0,004 % in eau de toilette
 - (c) 0,002 % in fragrance cream
 - (d) 0,001 % in rinse-off products
 - (e) 0,0002 % in other leave-on products and oral hygiene products.]

Editorial Information

- X1 Substituted by Corrigendum to Commission Directive 2003/83/EC of 24 September 2003 adapting to technical progress Annexes II, III and VI to Council Directive 76/768/EEC on the approximation of the laws of Member States relating to cosmetic products (Official Journal of the European Union L 238 of 25 September 2003).
- X2 Substituted by Corrigendum to the twenty-sixth Commission Directive 2002/34/EC of 15 April 2002 adapting to technical progress Annexes II, III and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Official Journal of the European Communities L 102 of 18 April 2002).

Textual Amendments

- F2 Deleted by Commission Directive of 20 February 1990 (90/121/EEC).
- F3 Inserted by Commission Directive of 30 March 1983 (83/191/EEC).
- **F4** Inserted by Commission Directive of 16 July 1985 (85/391/EEC).
- F5 Substituted by Commission Directive 2003/83/EC of 24 September 2003 adapting to technical progress Annexes II, III and VI to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F6** Inserted by Commission Directive of 26 March 1986 (86/199/EEC).
- F7 Inserted by Commission Directive of 12 March 1991 (91/184/EEC).
- F8 Deleted by Commission Directive of 21 February 1989 (89/174/EEC).
- **F9** Inserted by Commission Directive of 20 February 1990 (90/121/EEC).
- **F10** Substituted by Commission Directive 2002/34/EC of 15 April 2002 adapting to technical progress Annexes II, III and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- F11 Inserted by Commission Directive of 18 July 1984 (84/415/EEC).
- F12 Deleted by Commission Directive of 2 March 1988 (88/233/EEC).
- F13 Inserted by Commission Directive of 10 July 1995 (95/34/EC).
- **F14** Deleted by Commission Directive 2000/11/EC of 10 March 2000 adapting to technical progress Annex II to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

- F15 Inserted by Commission Directive 2000/11/EC of 10 March 2000 adapting to technical progress Annex II to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- F16 Inserted by Commission Directive of 29 June 1983 (83/341/EEC).
- F17 Inserted by Commission Directive of 28 February 1986 (86/179/EEC).
- F18 Inserted by Commission Directive of 2 February 1987 (87/137/EEC).
- F19 Inserted by Commission Directive of 2 March 1988 (88/233/EEC).
- **F20** Inserted by Commission Directive of 21 February 1989 (89/174/EEC).
- **F21** Deleted by Commission Directive 2003/83/EC of 24 September 2003 adapting to technical progress Annexes II, III and VI to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- F22 Inserted by Commission Directive of 21 October 1992 (92/86/EEC).
- F23 Inserted by Commission Directive of 22 June 1993 (93/47/EEC).
- **F24** Inserted by Commission Directive of 29 June 1994 (94/32/EC).
- F25 Deleted by Commission Directive of 14 July 1997 (97/45/EC).
- F26 Inserted by Commission Directive of 25 June 1996 (96/41/EC).
- F27 Inserted by Commission Directive of 5 March 1998 (98/16/EC).
- **F28** Substituted by Commission Directive 2003/1/EC of 6 January 2003 adapting to technical progress Annex II to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F29** Substituted by Commission Directive 2000/6/EC of 29 February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F30** Inserted by Commission Directive of 14 July 1997 (97/45/EC).
- **F31** Inserted by Commission Directive of 3 September 1998 (98/62/EC).
- **F32** Inserted by Commission Directive 2002/34/EC of 15 April 2002 adapting to technical progress Annexes II, III and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).



[F1PART 1 U.K.

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

[F1Reference	Substance	Restrictions	Conditions		
number		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	of use and warnings which must be printed on the label
a	b	c	d	e	f
[^{F29} 1a	Boric acid, borates and tetraborates	(a) Talc	(a) 5 % (by	(a)	(a)

mass/	1.	Not	1.	Not
mass		to		to
as		be		be
boric		used		used
acid)		in		for
uciaj		produ	icte	children
		for	icis	under
		child		3
		under		years
		3		of
		years		age
		of	2.	Not
		age		to
	2.	Not		be
		to		used
		be		on
		used		peeling
		on		or
		peelir	ng	irritated
		or	-o	skin
		irritat	aH	Not
		skin	Cu	to
		if		be
		the		used
			entration	for
		of		children
		free		under
		solub		3
		borate		years
		excee		of
		1,5 %)	age
		(by	2.	Not
		mass	1	to
		mass		be
		as		used
		boric		on
		acid)		peeling
	1.	Not		
	1.	to		or irritated
		be		skin
				SKIII
		used		
		in		
		produ	icts	
		for		
		childr		
		under	•	
		3		
		years		
		of		
		age		
	2.	Not		
		to		
		be		
ļ		DC		

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				used on peeling or irritated skin if the concentrat of free soluble borates exceeds 1,5 % (by mass/ mass as boric acid)	ion
(b)	Produ (bs) for all hygiène	0,1 % (by mass/mass as boric acid)	(b) 1.	Not 1. to be used in 2. products for children under 3 years of age Not to be 1. used in products for 2. children under 3 years of age	Not to be swallowed Not to be used for children under 3 years of age Not to be swallowed Not to be used for children under 3 years

					of age
produ (exclu bath produ	icts ading	3 % (by mass/ mass as	(c) 1.	Not 1. to be used in	Not to be used for
hair wavir		acid)		products for children under 3 years	childre under 3 years of age
			2.	age Not to be used on	Not to be used on peeling or irritate
				or irritated skin if the	skin Not to be used
				of free soluble borates exceeds 1,5 % (by 2.	childre under 3 years of age Not
			1.	mass/ mass as boric acid) Not	to be used on peeling or
				to be used in products for children under	irritate skin
	produ (exclubath produ and hair wavir	products and	products (by (excluding mass/bath mass products as and boric hair acid) waving	products (by (excluding mass) bath mass products as and boric hair acid) waving products) 2.	products (by (excluding mass) bath mass products as and boric hair acid) waving products) 2. Not to be used on peeling or irritateld skin if the concentration of free soluble borates exceeds 1,5 % (by 2. mass/mass as boric acid) 1. Not to be used in products for children under 3 and peeling or irritateld skin if the concentration of free soluble borates exceeds 1,5 % (by 2. mass/mass as boric acid) 1. Not to be used in products for children

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						2.	of age Not to be used on peelir or irritat skin if the conce of free solub borate excee 1,5 % (by mass/mass as boric acid)	entration le es ds	
1b	Tetraborates	(a)	Bath produ	(a) icts	18 % (by mass/mass as boric acid)	,	Not to be used in produ for childi under 3 years of age	en	Not to be used of bathing children under 3 years of age
		(b)	Hair wavii produ	ng	8 % (by mass/mass as boric acid)	r		(b)	Rinse well]]
[^{F19} 2a	Thioglycollic acid and its salts	(a)	Hair wavii or	ng		(a) (b) (c):	The direct for	(a): ions	Contains thioglycolate

		_	straig produ gener use		8 % ready for use pH 7 to 9,5	nati or offi lang mu	wn — ional cial guage(s) st —	Follow the instructions Keep out of reach of children For
		_	profe use	 ssional	ready for use pH 7 to 9,5	inco the foll sen — Avo	tac t	professional use only (c): Contains thioglycolate Follow the
		(b)	Depil	atories	5 % ready for use pH 7 to 12,7	eye In the eve of con witi	s — nt tact h	instructions Keep out of reach of children
			Other hair- caire produ which are remo after applie	acts h	ges d as	imr witi pler of wat and see adv — We suit glo ((a) and (c) onl	mediately h nty er k dical rice ar eable	
2b	Thioglycollic acid esters	Hair waving o straighter products:	ning			The directions for use drawn up in the national		Contains thioglycolate Follow the instructions
		_	gener use	a l	8 % ready for use	or official		Keep out of reach

			pH 6 to 9,5	incorporate the following sentences:	of children
		— profe	ssional 11 % read for use pH 6 to 9,5		tization professional use only
			The abovemention percentages are calculated as thioglycollic acid]	 Avoi conta with eyes In the even of conta with eyes rinse 	d d det t t ediately y t cal ce
[F13	Oxalic acid, its esters and alcaline salts	Hair care products	5 %		For professional use only
4	Ammonia		6 % calculated as NH ₃		Above 2 %: contains ammonia
5	Tosylchloramic sodium (*)	de	0.2 %		
6	Chlorates of alkali metals	(a) Tooth (b) Other uses	(b) 3 %		
7	Dichlorometha	ne	35 %	0·2 % as maximum	

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8	[F10m- and p- Phenylenedian their N- substituted	Oxidizing agents for hair dyeing	(when mixed with 1,1,1-trichloroethane total concentration must not exceed 35 %) 6 % calculated as free base	impurity content		
	derivatives and their salts; N-substituted derivatives of o-Phenylenediam with the exception of those derivatives listed elsewhere in this Annex]	(a) gener use	al		(a)	Can cause an allergic reaction. [F33]Contains phenylenediamines. Do not use to dye eyelashes or eyebrows
		(b) profeuse	ssional		(b)	For professional use only. Contains phenylenediamines. Can cause an allergic reaction. [F ³³][F ²³ Wear suitable gloves.]
9	their <i>N</i> -substituted derivatives	Paidingines, colouring agents for hair dyeing	10 % calculated as free base			
	and their salts ^a with the exception of substance	(a) gener use	al		(a)	Can cause an allergic

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	No 364 in Annex II]				reaction. [F33]Contains phenylenediamines. Do not use to dye eyelashes or eyebrows
		(b) profe use	ssional	(b)	For professional use only. Contains phenylenediamines. Can cause en allergic reaction. [F33][F23]Wear suitable gloves.]
10	Diaminopheno	Sxidizing colouring agents for hair dyeing	10 % calculated as free base		
		(a) gener use	al	(a)	Can cause an allergic reaction. [F33]Contains diaminophenols. Do not use to dye eyelashes or eyebrows
		(b) profe use	ssional	(b)	For professional use only.

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				Contain diaming Can cause allergic reaction [F33] [F23Wear suitable gloves.]]	ophenols.
[^{F18} 11	Dichlorophen (*)		0,5 %	Contains dichlorophen]	
[^{F22} 12		(a) Hair- caire prepa	12 % of H ₂ O ₂ (40 volumes), present or rations released	[F23(a): Wear suitable gloves]	
		(b) Skin-care prepa	4 % of H ₂ O ₂ , present or released rations	(a) (b) Contair (c): hydrogo peroxid	en
	carbamide peroxide and zinc peroxide	(c) Nail harde prepa	2 % of H ₂ O ₂ , present or ining released rations	Avoid contact with eyes. Rinse immediately if product comes into contact with them	
		(d) Oral hygie produ	0,1 % of H ₂ O ₂ , present or released	1	
[^{F1} 13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde	Protect cuticles with grease or oil. Contains formaldehyde ^b .]	
[F514	Hydroquinone	(a) Oxid colou agent for hair- dying		(a) 1. —	Do not use to dye eyelashes or eyebrows

		1.	Gene use	ral		_	Rinse the eyes immedia if the product comes into contact with them Contains hydroqui	
		2.	Profe use	essional		2.		For professional use only Contains hydroquinone Rinse the eyes immediately if the product comes into contact with them
		(b)	Artif nail syste	0,02 % (after character) (afte	Professional use only	(b)	_	For professional use only Avoid skin contact Read directions for use carefully]
[^{F26} 15a	Potassium or sodium hydroxide	(a)	Nail cutic solve	le by	ht ^d	(a)	Contains alkali. Avoid contact with	

							eyes. Can cause blindness. Keep out of reach of children
	(b)	Hair straig	(b) htener			(b)	
	1.	Gene use	rál	2 % by weigh	nt ^d	1.	Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
	2.	Profe use	s≩ional	4,5 % by weigh		2.	For professional use only. Avoid contact with eyes. Can cause blindness.
	(c) 	pH adjus depila	(c) ter atories	Up to pH 12,7		(c)	Keep out of reach of children. Avoid contact with eyes

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		use as pH		Up to pH 11				
[^{F10} 15b	Lithium hydroxide	(a) Ha	ir (a)				(a)	
		1. Ge	nerál	2 % the weight			1. Conta alkali Avoid contact with eyes Can cause blindness Keep out of reach of children	ins
		2. Prouse	ofes2ional	4,5 % weigh			2. For profes use only Avoid contact with eyes Can cause blindness	ssional
		for	ster —		(b)	pH value not to excee pH 12,7	Keep out of reach of whildren Avoid contact	ins
		(for ring off	uster r se-		(c)	pH value not to excee pH 11		
15c	Calcium hydroxide	Hair straighteners containing two	(a)	7 % by weigh	nt		(a) Conta alkali Avoid contact with eyes	ins

		components: calcium hydroxide and a guanidine salt	calciu hydro		Keep out of reach of children Can cause blindness
		(b) pH ajuste for depile	er — atories	(b) pH value not to excee pH 12,7	(b) Contains alkali Keep out of reach of whildren Avoid contact with eyes
		(c) Other uses (e.g. pH adjus proce aid)	ter,	(c) pH value not to excee pH 11	
[^{F1} [^{F10} 16	1-Naphthol (CAS No 90-15-3) and its salts	Oxidising colouring agents for hair dyening	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergie reaction]
17	Sodium nitrite	Rust inhibitor	0,2 %	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0,3 %		
19	Phenol and its alkali salts	Soaps and shampoos	1 % calculated as phenol		Contains phenol
[F33]					
21	Quinine and its salts	(a) Sham	(a) 0,5 % calculas		

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		(b)	Hair lotion	(b) s	quinii base 0,2 % calcu as quinii base	lated		
22	Resorcinol ^c	(a)	Oxidi colou agent for hair dyein	ring	5 %		(a)	
		1.	gener	al			Rinse ey immedia if produc comes ir contact v them	itely et nto
		2.	profe use	ssional			Rinse ey immedia if product comes in contact withem	itely et ito

		(b) Hair lotion and		0	(b)	Contains resorcinol
		sham	poos			
23	(a) Alka sulph		a(to)ries 2 % calcu as sulph pH ≤	ur	(a)	Keep out of reach of children. Avoid contact with eyes
	(b) Alka earth sulph		a(to)ries 6 % calcu as sulph pH ≤	ur	(b)	Keep out of reach of children. Avoid contact with eyes
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulpho and zinc pyrithione	nate	1 % calculated as zinc			
25	Zinc 4- hydroxybenzer sulphonate	Deodorants, antiperspirants and astringent lotions			Avoid co with eye	
26	Sodium monofluoroph	Oral hygiene sprhatæts	0,15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F		Contains ammoni monoflu	

		concentration must not exceed 0,15 %	
27	Sodium Ditto monofluorophosphate	0,15 % Ditto	Contains sodium monofluorophosphate
28	Potassium Ditto monofluorophosphate	0,15 % Ditto	Contains potassium monofluorophosphate
29	Calcium Ditto monofluorophosphate	0,15 % Ditto	Contains calcium monofluorophosphate
30	Calcium Ditto fluoride	0,15 % Ditto	Contains calcium fluoride
31	Sodium Ditto fluoride	0,15 % Ditto	Contains sodium fluoride
32	Potassium Ditto fluoride	0,15 % Ditto	Contains potassium fluoride
33	Ammonium Ditto fluoride	0,15 % Ditto	Contains ammonium fluoride
34	Aluminium Ditto fluoride	0,15 % Ditto	Contains aluminium fluoride
35	Stannous Ditto fluoride	0,15 % Ditto	Contains stannous fluoride
36	Hexadecyl ammonium fluoride Ditto	0,15 % Ditto	Contains hexadecyl ammonium fluoride
37	3-(N- Ditto Hexadecyl-N-2-hydroxyethylammonio propylbis (2-hydroxyethyl) ammonium difluoride	0,15 % Ditto	Contains 3-(N- Hexadecyl-N-2- hydroxyethylammonio) propylbis (2- hydroxyethyl) ammonium difluoride
38	NN'N'- Ditto Tris(polyoxyethylene)-	0,15 % Ditto	Contains <i>NN'N'</i> - tris(polyoxyethylene)-A

	hexadecylprop dihydrofluorid				hexadecylpropylenediam 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		Containes (SIC! Contains) magnesium fluorosilicate]
(^{F17} 44	1,3-Bis (hydroxymethy thione	(b) Nail-care	rations 2 %	in aeros	
				as applic must be less than 4	
[^{F1} 45	Benzyl alcohol	Solvents, perfumes and flavourings			1
[^{F3} 46	6- methylcoumar	Oral hygiene iproducts	0,003 %		1
[^{F11} 47	Nicomethanol hydrofluoride	Oral hygiene products	0,15 % calculated as F When mixed with other		Contains nicomethanol hydrofluoride

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			fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %			
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]
[^{F4} 49	Selenium disulphide	Antidandruff shampoos	1 %		_	Contains selenium disulphide Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxyde complexes Al _x Zr(OH) _y Cl ₂ and the aluminium zirconium chloride sydroxide glycine complexes	Antiperspirants	anhydrous aluminium zirconium chloride hydroxide 5,4 % as zirconium	aton to that of	skin] ber ninium ns onium	ed

				2.	an 10 The ratio of the number of (Al + Zr) atoms to
				3.	that of chlorine atoms must be between 0,9 and 2,1 Prohibited
					in aerosol dispensers (sprays)
[^{F19} 51	Quinolin-8- ol and bis (8-hydroxy- quinolium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations	0,3 % calculated as base		
		Stabilizer for hydrogen peroxide in non-rinse- off hair-care preparations	0,03 % calculated as base]
[^{F18} 52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % ethanol and isopropyl acohol]
[F1953	Etidronic acid and its salts (1-	(a) Haircare	1,5 % expressed as etidronic acid		[^{F8}]
	hydroxyethylid di- phosphonic	(b) Soap	0,2 % expressed as etidronic acid		

	acid and its salts)				
54	1-Phenoxy- propan-2-ol	— Rinse off produ		As a preservative, see Annex VI, Part 1, No 43	
		— Prohi in oral hygie produ	ene]
[^{F9} 55	Lead acetate	Only for hair-dyeing	0,6 % calculated in lead		Keep away from children. Avoid all contact with the eyes. Wash hands after use. Contains lead acetate. Do not use to dye eyelashes, eyebrows or moustasches. If irritation develops, discountinue use.]
[^{F7} 56	Magnesium fluoride	Dental hygiene products	0,15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains magnesium fluoride]
[^{F31} 57	Strontium chloride hexahydrate	(a) Tooth	3,5 %, Calculated as strontium. When mixed with other permitted		Contains strontium chloride. Frequent use by children is not advisable

			strontium products the total strontium content must not exceed 3,5 %	1	
		face	calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 2,1 %	J	
[F2258	Strontium acetate hemihydrate	Toothpaste	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 %	Contains strontius acetate. Frequen by child not advi	n t use ren is
[^{F24} 59	Talc: Hydrated magnesium silicate	(a) Power production to be used for child under three years of age	ucts ded ren	[^{x3} (a)	Keep powder away from children's nose and mouth]]
		(b) other prode			

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Patty acid dialkylamides and dialkanolamides Maximum secondary amine content:					
dialkylamides and dialkanolamides dialkylamides secondary amine use with nitrosating systems	I ^{F5} 60	Fatty acid	Maximum	_	Do
amine content: with nitrosating systems	1 00		I		
Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine content: 5 % (applies to raw materials) Maximum nitrosamine content: 50 μg/kg Maximum secondary amine content: 0,5 % Maximum nitrosamine content: 0,5 % Maximum secondary amine content: 0,5 % Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum nitrosamine content: 50 μg/kg M					use
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Monoalkylamines, monoalkanolamines and their salts					5 %
Monoalkylamines, monoalkanolamines and their salts					(applies
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Maximum nitrosamine content: 50 μg/kg Maximum secondary and their salts Maximum secondary amine content: 0,5 % Maximum secondary amine content: 50 μg/kg Maximum nitrosamine content: 50 μg/kg Maximum secondary kg Maximum secondary amine content: 50 μg/kg Maximum nitrosamine content: 50 μg/kg Maximum secondary kg Maximum secondary amine content: 50 μg/kg Maximum secondary kg Maximum secondary kg Maximum secondary kg Maximum secondary amine content: 50 μg/kg Maximum secondary kg Maximum secondary kg Maximum secondary amine content: 50 μg/kg Maximum secondary kg Maximum secondary amine content: 50 μg/kg Maximum secondary amine content secondary amine secondary amine content secondary amine secondary am					materials)
Content: 50 μg/kg Reep in nitrite-free containers				_	
61 Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine use content: with nitrosating systems Minimum purity: 99 % Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum nitrosamine content: 50 µg/kg Maximum nitrosamine content: 50 µg/kg Mexep in materials in mitrosamine content: 50 µg/kg Mexep in mitrosamine content					nitrosamine
61 Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine use content: with nitrosating systems — Maximum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in					content:
61 Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine use content: with nitrosating systems — Maximum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in					50 μg/
Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine content:					
61 Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine content: 0,5 % mitrosating systems — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in				_	
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Monoalkylamines, monoalkanolamines and their salts Maximum secondary amine use content: with nitrosating systems — Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 μg/kg — Keep in					free
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monoalkanolamines and their salts secondary amine use content: with nitrosating systems Minimum purity: 99 % Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum nitrosamine content: 50 µg/kg Meg Keep in	61	Monoalkylamines	Maximum	_	Do
amine content: 0,5 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in	O I	monoalkanolamines			
content: 0,5 % — Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/ kg — Keep in					
0,5 % nitrosating systems Minimum purity: 99 % Maximum secondary amine content: 0,5 % (applies to raw materials) Maximum nitrosamine content: 50 μg/kg Keep in			I		
systems Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/ kg — Keep in					
- Minimum purity: 99 % - Maximum secondary amine content: 0,5 % (applies to raw materials) - Maximum nitrosamine content: 50 μg/ kg - Keep in			,		
purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in				_	
- Maximum secondary amine content: 0,5 % (applies to raw materials) - Maximum nitrosamine content: 50 μg/kg - Keep in					
secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/ kg — Keep in					
amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					Maximum
amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					secondary
0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					
(applies to raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					content:
to raw materials) — Maximum nitrosamine content: 50 µg/ kg — Keep in					0,5 %
raw materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					(applies
materials) — Maximum nitrosamine content: 50 μg/ kg — Keep in					to
— Maximum nitrosamine content: 50 μg/ kg — Keep in					
nitrosamine content: 50 μg/ kg — Keep in					
content: 50 μg/ kg				_	
50 μg/ kg — Keep in					
Keep in					
— Keep in					
in in					ka
nitrit¢-				_	Keep
					Keep in

				free conta	iners	
62	Trialkylamine trialkanolamir and their salts	nesa) Non-	ucts	not use with nitro syste Mini purit 99 % Maxi secon amin conte 0,5 % (appl to raw mate Maxi nitro conte 50 µg kg Keep in nitrit free	mum y: imum ndary e ent: iies rials) imum samine ent:	
[F2463	Strontium hydroxide	pH-regulator in depilatory products	3,5 % calculated as strontium, max. pH of 12,7		_	Keep out of reach of children Avoid contact with the eyes
64	Strontium peroxide	Rinse-off hair care preparations professional use	4,5 % calculated as strontium in the readyfor-use preparation	All products must meet the hydrogen peroxide release requirements	_	Avoid contact with eyes Rinse eyes immediatel if product

								_	comes into contact with them For professional use only Wear suitable gloves]
[F3465	Benzalkonium Chloride, bromide and saccharinate	(a)	Rinse- off hair (head) care produ)	3 % (as benza chlori	(a) alkonium ide)	of benza chloridate chloridate chloridate chloridate chain and sacch with an alkyl chain of C ₁₄ , or less must not exceed 0,1 % (as	entrations alkonium ide, ide arinate	Avoid contact with the eyes
		(b)	Other produ		0,1 % (as benza chlori	lkonium		(b)	Avoid contact with the eyes]
[^{F32} 66	Polyacrylamide	es (a)	Body- care leave- on produ			(a)	Maxiresidu acryla conte	ıal amide	

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		(b) Other cosm produ	etic	resi	ximum dual vlamide tent
[F3567	Amyl cinnamal (CAS No 122-40-7)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,00 in leave on processing proces	01 % re- ducts
68	Benzyl alcohol (CAS No 100-51-6)			in leav on	01 % re- ducts

] I	_ <u>~</u> ~
		off
		products
69	Cinnamyl	The presence
	alcohol	of the
	(CAS No	substance
	104-54-1)	must be
	,	indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		in
		leave-
		on
		products
		0,01 %
		in
		rinse-
		off
		products
70	Citral	The presence
	(CAS No	of the
	5392-40-5)	substance
		must be
		indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		in
		leave-
		on
		products
		— 0,01 %
		- 0,01 70 in
		rinse-
		off
		products
71	Eugenol	The presence
	(CAS No	of the
	97-53-0)	substance
	/	must be
		indicated in
	1	maroutou m

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			the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on produ — 0,010 in rinse-off produ	cts %
72	Hydroxy-citronellal (CAS No 107-75-5)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production of the presence of the production of the production of the presence	cts %
73	Isoeugenol (CAS No 97-54-1)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds:	

			leave on	
			— produ 0,01 in	
			rinse off	_
			prod	ucts
74	Amylcin namyl alcohol (CAS No 101-85-9)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on	
			— production 0,01 in rinse off	% -
75	Benzyl		The presence	ucts
//3	salicylate (CAS No 118-58-1)		of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production on the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production on the leave on the lea	ucts %
			rinse	†

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	I	_ cc
		off
		products
76	Cinnamal	The presence
	(CAS No	of the
	104-55-2)	substance
		must be
		indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		in
		leave-
		on
		products
		0,01 %
		in .
		rinse-
		off
		products
77	Coumarin	The presence
	(CAS No	of the
	91-64-5)	substance
	,	must be
		indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		- 0,001 70 in
		leave-
		on
		products
		in
		rinse-
		off
		products
78	Geraniol	The presence
	(CAS No	of the
	106-24-1)	substance
		must be
		indicated in
		marcated in

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				the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production production in contraction in contrac	acts %
				off produ	
79	(CAS No 31906-04-4)	yclohexenecarbo	oxaldehyde	The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production of the prod	% - ucts %
80	Anisyl alcohol (CAS No 105-13-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds:	

			- 0,001 % in leave- on products - 0,01 % in
			rinse- off products
81	Benzyl cinnamate (CAS No 103-41-3)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off
82	Farnesol (CAS No 4602-84-0)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-

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	I I	CC
		off
		products
83	2-(4-tert-	The presence
	Butylbenzyl)	of the
	propionaldehyde	substance
	(CAS No	must be
	80-54-6)	indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		leave-
		on products
		products
		— 0,01 %
		in
		rinse-
		off
		products
84	Linalool	The presence
	(CAS No	of the
	78-70-6)	substance
	,	must be
		indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		in
		leave-
		on
		products
		— 0,01 %
		in
		rinse-
		off
		products
85	Benzyl	The presence
	benzoate	of the
	(CAS No	substance
	120-51-4)	must be
		indicated in
	I I	maiouted iii

			the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on produ	- ucts
			— 0,01° in rinse- off produ	
86	Citronellol (CAS No 106-22-9)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production of the pr	- acts //o
87	Hexyl cinnam- aldehyde (CAS No 101-86-0)		The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds:	

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			ir le o p o ir ri o p	eave- n roducts ,01 % n nse- ff roducts
88	d-Limonene (CAS No 5989-27-5)		ir le o p p ir ri o	in) s on ,001 % n eave- n roducts ,01 %
89	Methyl heptin carbonate (CAS No 111-12-6)		ir le o p p o ir	in) s on ,001 % n eave- n roducts ,01 %

	1	- cc
		off
		products
90	3-Methyl-4-	The presence
	(2,6,6-tri-	of the
	methyl-2-	substance
	cyclohexen-1-	must be
	yl)-3-buten-2-	indicated in
	one	the list of
	(CAS No	ingredients
	127-51-5)	referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		— 0,001 %
		in
		leave-
		on
		products
		in
		rinse-
		off
		products
0.1	0.1	
91	Oak moss	The presence
	extract	of the
	(CAS No	substance
	90028-68-5)	must be
		indicated in
		the list of
		ingredients
		referred to in
		Article 6(1)
		(g) when its
		concentration
		exceeds:
		in
		leave-
		on
		products
		— 0,01 %
		in
		rinse-
		off
		products
92	Treemoss	The presence]
- -	extract	of the
	(CAS No	substance
	90028-67-4)	must be
	70020 07-4)	indicated in
		marcarea m

				the list of ingredients referred to in Article 6(1) (g) when its concentration exceeds: — 0,001 in leave on production production off production of the pro	ects %
[^{F36} 93	2,4-Diamino- pyrimidine-3- oxide (CAS No 74638-76-9)	Hair care formulations	1,5 %		
94	Benzoyl peroxide	Artificial nail systems	0,7 % (after mixing)	Professional use only	 For professional use only Avoid skin contact Read directions for use carefully
95	Hydroquinone methylether	Artificial nail systems	0,02 % (after mixing for use)	Professional use only	 For professional use only Avoid skin contact Read directions for use carefully

a These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.

b Only if the concentration exceeds 0,05 %.

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

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- d [F26]The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column d.]
- e [F32These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1.1
- f [F32The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column d.]]

Editorial Information

X3 Inserted by Corrigendum, OJ No L 273, 25. 10. 1994, p. 38 (94/32/EC).

Textual Amendments

- **F33** Deleted by Commission Directive of 21 October 1992 (92/86/EEC).
- F34 Inserted by Commission Directive 2000/6/EC of 29 February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F35** Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F36** Inserted by Commission Directive 2003/83/EC of 24 September 2003 adapting to technical progress Annexes II, III and VI to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

[^{F6}[^{F37}Part 2] U.K.

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Reference	Substance	Restriction	S	Conditions	Allowed	
number		Field of application and/or use	Maximum authorized concentrati in the finished cosmetic product		of use and warnings itsyhich must be printed on the label	until
a	b	c	d	e	f	g
[^{F32} 1	Basic Blue 7 (CAS No 2390-60-5)	Non- oxidising colouring agents for hair dyeing	0,2 %		Can cause allergic reaction	30.9.2004
2	2-Amino-3- nitrophenol (CAS No 603-85-0) and its salts	col	idajing 3,0 ouring ents	In combination with hydrogen peroxide the	cau alle	

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		(b) No oxi col age for hai	r(b) 3,0 dising ouring ents	maximum use concentration upon application is 1,5 %		
3	4-Amino-3- nitrophenol (CAS No 610-81-1) and its salts	col age for hai dye	r eing	In combination with hydrogen peroxide the maximum use	alle rea	
		oxi col age for hai	dising ouring ents	% oncentration upon application is 1,5 %	1	
4	2,7- Naphthalene (CAS no 582-17-2) and its salts	Oxidising diolouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %	n	30.9.2004
5	m- Aminopheno (CAS no 591-27-5) and its salts	Oxidising lcolouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004

6	2,6- Dihydroxy-3 dimethylpyri (CAS No 84540-47-6) and its salts		2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004
7	4- Hydroxyprop nitrophenol (CAS No 92952-81-3) and its salts	(b) No ox colar for ha	ents ir eing in(b) 2,6 idising ouring ents	In combination with hydrogen peroxide the maximum use concentration upon application is 2,6 %	cau alle rea	
8	6- Nitro-2,5- pyridinedian (CAS No 69825-83-8) and its salts	Non- oxidising nindouring agent for hair dyeing	3,0 %		Can cause allergic reaction	30.9.2004
9	HC Blue No 11 (CAS No 23920-15-2) and its salts	co ag for ha dy	ir eing	with hydrogen peroxide the maximum use	alle rea	
		ox co ag foi ha	idising ouring ents · ir eing	concentration upon application is 1,5 %	h	
10	Hydroxyethy nitro-p-toluidine	(a) Ox	i (ai) ing 2,0 louring	In combination with	(a) (b) Ca	

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	(CAS No 100418-33-5 and its salts) for hai dye (b) No oxi col age for hai	r(b) 1,0 dising ouring	hydrogen peroxide the maximum use concentration upon application is 1,0 %	rea	ergic ction
11	2- Hydroxyethy acid (CAS No 99610-72-7) and its salts	(b) No oxi col age for hai	ouring ents r eing n(b) 2,0 dising ouring ents	In Combination with hydrogen peroxide the maximum use Concentration upon application is 1,5 %	cau alle rea	
12	p- Methylamino (CAS No 150-75-4) and its salts	Oxidising phknaing agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	reaction	30.9.2004
13	2,4- Diamino-5- methylpheno (CAS No 141614-05-3 and its salts	hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	reaction	30.9.2004

14	HC Violet No 2 CAS No 104226-19-9 and its salts	Non- oxidising colouring)agent for hair dyeing	2,0 %			30.9.2004
15	Hydroxyethy dinitro-p- anisidine (CAS No 122252-11-3 and its salts	oxidising colouring agent for	3,0 %		Can cause allergic reaction	30.9.2004
16	HC Blue No 12 (CAS No 104516-93-0 and its salts	col age for hai	ouring ents	In combination with hydrogen peroxide the maximum	cau alle	
		oxi col age for hai	dising ouring ents	use %ncentration upon application is 0,75 %	n	
17	[X42,4-Diamino-5 methyphenet (CAS No 113715-25-6 and its salts]	hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004
18	1,3-Bis- (2,4- diaminopher (CAS No 81892-72-0) and its salts	Oxidising colouring colouring coge pts of the colouring hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004

19	[X43- Amino-2,4- dichloropher (CAS No 61693-43-4) and its salts]	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004
20	Phenyl methyl pyrazolone (CAS No 89-25-8) and its salts	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %	n	30.9.2004
21	2- Methyl-5- hydroxyethy (CAS No 55302-96-0) and its salts	Oxidising colouring lagintspfumol hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004
22	Hydroxyben (CAS No 26021-57-8) and its salts	zOxiolishngine colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	reaction	30.9.2004

23	1,7- Naphthalene (CAS No 575-38-2) and its salts	Oxidising diolouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %	reaction	30.9.2004
24	HC Yellow No 10 (CAS No 109023-83-8 and its salts	Non- oxidising colouring agents for hair dyeing	0,2 %			30.9.2004
25	2,6- Dimethoxy-3 pyridinedian (CAS No 85679-78-3) and its salts		0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %	reaction	30.9.2004
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non- oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
27	HC Violet No 1 (CAS No 82576-75-8) and its salts	col age for hai dye (b) No oxi col age for hai	reing n(b) 0,5 dising ouring ents	In Combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004

28	3- Non- Methylamino okidi nitro- color phenoxyethamgen (CAS No hair of 59820-63-2) and its salts	sing Iring		30.9.2004
29	2-Hydroxy- ethylamino-5 oxidi nitro- anisole (CAS No 66095-81-6) and its salts	sing Iring		30.9.2004
30	2-Chloro-5- nitro-N- hydroxyethyl- p- phenylenediamine (CAS No 50610-28-1) and its salts (b)	Oxidaying colouring agents for hair dyeing Non(b) oxidising colouring agents for hair dyeing	2,0 Combination with hydrogen peroxide the maximum use 1,0 Concentration upon application is 1,0 %	30.9.2004
31	[X4HC Red No 13 (CAS No 94158-13-1) and its salts] (a)	Oxidasing colouring agents for hair dyeing Non(b) oxidising colouring agents for hair dyeing	2,5 Combination with hydrogen peroxide the maximum use 2,5 Concentration upon application is 1,25 %	30.9.2004
32	1,5- Oxid Naphthalenediolou (CAS No agent 83-56-7) hair o	ising 1,0 %	In combination with hydrogen peroxide the maximum	30.9.2004

33	Hydroxyprophis (N-hydroxyethy p-phenylenedia (CAS No 128729-30-6 and its salts	colouring lagents for hair dyeing amine)	3,0 %	use concentration upon application is 0,5 % In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
34	o- Aminopheno (CAS No 95-55-6) and its salts	Oxidising Scolouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	1	30.9.2004
35	4-Amino-2- hydroxytoluc (CAS No 2835-95-2) and its salts		3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	n	30.9.2004
36	[X42,4-Diaminopher (CAS No 66422-95-5) and its salts]	agents for	4,0 %	In combination with hydrogen peroxide the maximum use concentration upon	1	30.9.2004

Council Directive of 27 July 1976 on the approximation of the laws of...

ANNEX III Part 2

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				application is 2,0 %	
37	2- Methylresor (CAS No 608-25-3) and its salts	Oxidising cindburing agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	30.9.2004
38	4-Aminom-cresol (CAS No 2835-99-6) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
39	2-Amino-4- hydroxyethy (CAS No 83763-47-7) and its salts	laolingangsole agents for	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
40	3,4- Diamino- benzoicacid (CAS No 619-05-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	30.9.2004

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41	6-Amino- o-cresol (CAS No 17672-22-9) and its salts	ng For	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
42	2- Oxidisi Aminomethy kolourin p- agents f aminophenol hair dye (CAS No 79352-72-0) and its salts	ng For	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
43	Hydroxyethy Axiidisi methyl-p-colourin aminophenol agents to hair dye 110952-46-0) and its salts	ng For	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
44	Hydroxyethy Os, Asisimethylenedioxoshnifii (CAS No 81329-90-0) and its salts	ng For	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	30.9.2004
45	[X4Acid Oxidisi Black 52 colouring		In combination	30.9.2004

	(CAS No 3618-58-4) and its salts]	agents for hair dyeing		with hydrogen peroxide the maximum use concentration upon application is 1,0 %	
46	2-Nitro-p- phenylenedia (CAS No 5307-14-2) and its salts	col ago for hai	ouring ents	In Combination with hydrogen peroxide the maximum	30.9.2004
		ox col age for hai	idising ouring ents	use concentration upon application is 0,15 %	
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non- oxidising colouring agents for hair dyeing	2,8 %		30.9.2004
48	3-Nitro-p- hydroxyethy (CAS No 65235-31-6) and its salts	ago for ha	ouring ents	In Combination with hydrogen peroxide the maximum	30.9.2004
		ox col age for ha	idising ouring ents	use concentration upon application is 3,0 %	
49	4- Nitrophenyl aminoethylu (CAS No 27080-42-8) and its salts	rea col	ouring	In combination with hydrogen peroxide the	30.9.2004

		(b)	hair dyeing Non(b) oxidising colouring agents for hair dyeing	0,5	maximum use concentration pon application is 0,25 %	
50	HC Red No 10 + HC Red No 11 (CAS No 95576-89-9 and its salts	(a) + 95576-9 (b)	Oxidaying colouring agents for hair dyeing Non(b) oxidising colouring agents for hair	1,0	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	30.9.2004
51	Yellow No 6 (CAS No 104333-00-8 and its salts	(a)) (b)	Oxidaying colouring agents for hair dyeing		In Combination with hydrogen peroxide the maximum use	30.9.2004
			oxidising colouring agents for hair dyeing	_,,	upon application is 1,0 %	
52	HC Yellow No 12 (CAS No 59320-13-7) and its salts	(a)	Oxidaying colouring agents for hair dyeing	1,0	In combination with hydrogen peroxide the maximum	30.9.2004
		(b)	Non(b) oxidising colouring	0,5	use concentration upon	

		for hai		application is 0,5 %	
53	[X4HC Blue No 10 (CAS No 102767-27-1 and its salts]	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	30.9.2004
54	HC Blue No 9 (CAS No 114087-47-1 and its salts	(b) No oxi col age for hai	ents r eing n(b) 1,0 dising ouring ents	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	30.9.2004
55	2-Chloro-6- ethylamino-4 nitrophenol (CAS No 131657-78-8 and its salts	col age for hai dye	ents r eing	In Combination with hydrogen peroxide the maximum use Concentration	30.9.2004
		col age for hai	ouring ents	upon application is 1,5 %	
56	2-Amino-6- chloro-4- nitrophenol (CAS No	col	idaying 2,0 ouring ents	In combination with hydrogen peroxide	30.9.2004

	6358-09-4) and its salts	(b) No ox co agg for ha	eing on(b) 2,0 idising ouring ents	the maximum use %oncentration upon application is 1,0 %	
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	co ag for ha dy	louring ents - ir eing	In combination with hydrogen peroxide the maximum use	30.9.2004
		co ag for ha	idising louring ents	upon application is 0,25 %	
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non- oxidising colouring agents for hair dyeing	2,0 %		30.9.2004
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non- oxidising colouring agents for hair dyeing	2,0 %		30.9.2004
60	Basic Violet 14 (CAS No 632-99-5) (CI 42510) and its salts	co ag for ha	louring ents	In combination with hydrogen peroxide the maximum	30.9.2004
		OX CO	idising louring ents	use concentration upon application is 0,15 %	

		hai dy	r eing			
61	Musk xylene (CAS no 81-15-2)	All cosmetic products, with the exception	(a)	1,0 % in fine fragrance		[F3830.9.2004]
	of oral care products (t	(b)	0,4 % in eau de toilette			
			(c)	0,03 % in other products		
62	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception	(a)	1,4 % in fine fragrance		[F3830.9.2004]
		of oral care products	(b)	0,56 % in eau de toilette		
			(c)	0,042 % in other products	11	

Editorial Information

X4 Substituted by Corrigendum to the Twenty-sixth Commission Directive 2002/34/EC of 15 April 2002 adapting to technical progress Annexes II, III and VII to Council Directive 76/748/EEC on the approximation of the laws of the Member States relating to cosmetic products (Official Journal of the European Communities L 102 of 18 April 2002).

Textual Amendments

F38 Substituted by Commission Directive 2003/16/EC of 19 February 2003 adapting to technical progress Annex III to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

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Textual Amendments

F37 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

ANNEX IV U.K.

[^{F17}[^{F37}PART 1] U.K.

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a

Field of application

Colour	Colour	Field o	Other			
index number or denomina	ion	1	2	3	4	limitations and requirement
10006	Green				X	
10020	Green			X		
10316°	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
[F39]						
12085°	Red	X				3 % maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	[F8]

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a Field of application 13015 Yellow X E 105 [F12] 14270 X E 103 Orange 14700 Red X 14720 X Red E 122 14815 Red X E 125 15510° Orange X X 15525 Red 15580 Red X [F39] 15620 Red X X 3 % Red $15630^{\rm c}$ maximum concentration in the finished product X [F8] 15800 Red Red X 15850° Red X 15865° 15880 Red X 15980 X E 111 Orange Yellow X E 110 15985° 16035 X Red X 16185 Red E 123 16230 Orange X X Red E 124 16255° 16290 Red X E 126 X Red 17200° 18050 Red X X 18130 Red 18690 Yellow X 18736 X Red

Field of app	plication				
18820	Yellow			X	
18965	Yellow	X			
19140°	Yellow	X			E 102
20040	Yellow			X	maximum 3,3'- dimethylbenzidine concentration in the colouring agent: 5 ppm
20170	Orange		X		
20470	Black			X	[F8]
21100	Yellow			X	maximum 3,3'- dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow			X	ditto
21230	Yellow		X		
24790	Red			X	
[^{F22} 26100	Red		X		Purity criteria: aniline $\leq 0,2 \%$ 2- naphtol $\leq 0,2 \%$ 4- aminoazobenzene $\leq 0,1 \%$ 1- (phenylazo)-2- naphtol $\leq 3 \%$ 1- [2- (phenylazo)phenylazo)phenylazonapthalenol

concentration

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LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a Field of application [F1727290° Red X 27755 X Black E 152 Black X E 151 28440 40215 X Orange 40800 X Orange 40820 Orange X E 160 e 40825 Orange X E 160 f 40850 Orange X E 161 g [F9X] [F2] 42045 Blue Blue X E 131 42051° 42053 Green X 42080 Blue X 42090 X Blue X 42100 Green X [F8] 42170 Green Violet 42510 X 42520 X Violet 5 ppm maximum concentration in the finished product [F2] 42735 Blue X 44045 [F9X] $[F^2]$ Blue 44090 X E 142 Green X 45100 Red [F39] [^{F39}] 45190 Violet X 45220 Red X 45350 Yellow X 6 % maximum

LIST OF 0	COLOURING	G AGENTS	ALLOWED F	OR USE IN COSME	ETIC PRODUCTS ^a
Field of ap	oplication				
					in the finished product
45370°	Orange	X			not more than 1 % 2-(6- hdroxy-3- oxo-3H- xanthen-9- y1) benzoic acid and 2 % 2- (bromo-6- hydroxy-3- oxo-3H- xanthen-9- yl) benzoic acid
45380°	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

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a

Field of a	pplication				
45410°	Red	X			ditto
45425	Red	X			not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 3 % 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45430°	Red	X			E 127 ditto
47000	Yellow		X		[F8]
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			

ion

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LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a Field of application 73385 Violet X [F33] 73900 Violet X 73915 Red X 74100 Blue X 74160 Blue X [F33] 74180 Blue X 74260 X Green 75100 Yellow X 75120 X Orange E 160 b 75125 Yellow X E 160 d X 75130 E 160 a Orange 75135 Yellow X E 161 d X 75170 White 75300 Yellow X E 100 75470 Red X E 120 X 75810 Green E 140 and E 141 X 77000 White E 173 77002 White X X 77004 White X 77007 Blue X 77015 Red 77120 White X 77163 White X X 77220 White E 170 77231 White X 77266 X Black X 77267 Black X 77268:1 Black E 153] X [F1877288 free from Green chromate

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LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS^a

Field of app	lication				
77289	Green	X			free from chromate ion]
[F1777346	Green	X			
77400	Brown	X			
77480	Brown	X			E 175
77489	Orange	X			E 172
77491	Red	X			E 172
77492	Yellow	X			E 172
77499	Black	X			E 172
77510	Blue	X			free from cyanide ions
77713	White	X			
77742	Violet	X			
77745	Red	X			
77820	White	X			E 174
77891	White	X			E 171
77947	White	X			
Lactoflavin	Yellow	X			E 101
Caramel	Brown	X			E 150
Capsanthin, capsorubin	Orange	X			Е 160 с
Beetroot red	Red	X			E 162
Anthocyanir	sRed	X			E 163
Aluminium, zinc, magnesium and calcium stearates	White	X			
Bromothymoblue	Blue			X	
Bromocreso	Green			X	1

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LIS	T OF CC	LOURING A	GENTS ALI	LOWED FOR	USE IN COS	SMETIC PRO	DUCTS ^a
Fiel	ld of appl	ication					
[^{F19} , 195	Acid red	Red			X]
a			ng agents using sub e are equally allow		ited under Annex	I or not excluded t	under Annex V
b	Colouring agents whose number is preceded by the letter 'E' in accordance whith the EEC Directive of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter 'E' has been deleted therefrom.						
c	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.						

Column 1	 Colouring agents allowed in all cosmetic products. Colouring agents allowed in all cosmetic products except those
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.]
	to come into contact only briefly with the skin.]

Textual Amendments

F39 Deleted by Commission Directive of 12 March 1991 (91/184/EEC).

[F17PART 2 U.K.

LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS^a

Field of application

Colour	Colour	Field of	application	[Other	Authorization
index number		1	2	3	4	limitation and	s valid until
or	4.					requirem	ents ^b
denomina	tion						
[F12]							
[F2]							
[F33]							
[F8]							
[F2]							
[F8]							
[F33]							
[F2]							

LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS^a

Field of application							
[F8]							
[^{F2}]							
[F12]							
[^{F2}]							
[F8]							
[^{F2}]							
[F12]							
[F33]							
[F8]							
[F33]							
[F8]							
[F40]							
[^{F12}]							
[F33]							

- a Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.
- b Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter 'E' has been deleted therefrom.

Column 1	 Colouring agents allowed in all cosmetic products. Colouring agents allowed in all cosmetic products except those
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-un and eve make-un 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.l

Textual Amendments

F40 Deleted by Commission Directive of 2 February 1987 (87/137/EEC).

ANNEX V U.K.

LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THE DIRECTIVE

1 $\begin{bmatrix} F^2 & \dots \end{bmatrix}$

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- $2 \qquad [^{\text{F40}}, \dots]$
- $3 \qquad [^{F2}, \ldots]$
- 4 $\begin{bmatrix} F^{41} & \cdots \end{bmatrix}$
- 5. [F²⁴Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex II, strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in Annex III, Part 1 and of strontium lakes, pigments and salts of the colouring agents listed with the reference (³) in Annex IV, Part 1.]
- 6 $[^{F2}, \ldots]$
- 7 $\begin{bmatrix} F39 \\ \dots \end{bmatrix}$
- $8 \qquad [F2,\ldots]$
- 9 $\begin{bmatrix} F42 & \dots \end{bmatrix}$
- $10 \qquad [^{\text{F43}}, \dots]$

Textual Amendments

- **F41** Deleted by Commission Directive of 29 June 1983 (83/341/EEC).
- **F42** Deleted by Commission Directive of 28 February 1986 (86/179/EEC).
- **F43** Deleted by Commission Directive of 18 July 1984 (84/415/EEC).

I^{F6}ANNEX VI U.K.

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN PREAMBLE

- 1. Preservatives are substances which may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.
- 2. The substances marked with the symbol (*) may also be added to cosmetic products in concentration other than those laid down in this Annex for other specific purposes apparent from the presentation of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.
- 3. Other substances used in the formulation of cosmetic products may also have antimicrobial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in this Annex.
- 4. For the purposes of this list:
 - "Salts' is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
 - 'Esters' is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.

5. All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %.

PART 1 U.K.

LIST OF PRESERVATIVES ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid, its salts and esters (*)	0,5 % (acid)		
2	Propionic acid and its salts (*)	2 % (acid)		
3	Salicylic acid and its salts (*)	0,5 % (acid)	Not to be used in preparations for children under three years of age, except for shampoos	Not to be used for children under three years of age ^a
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)	
[^{F40}]				
7	Biphenyl-2-ol (o-phenylphenol) and its salts (*)	0,2 % expressed as the phenol		
8	Pyrithione zinc (INN) (*)	0,5 %	Authorized in products rinsed off Forbidden in	

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

			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 (*)	4 % (acid) for 1 ester, 0,8 % (acid) for mixtures of esters		
13	3-Acetyl-6- methylpyran-2,4 (3H)-dione (Dehydracetic acid) and its salts	0,6 % (acid)	Prohibited in aerosol dispensers (sprays)	
[^{F24} 14	Formic acid and its sodium salt (+)	0,5 % (expressed as acid)]
[F615	3,3'- Dibromo-4,4'- hexamethylenedic benzamidine (Dibromohexamic and its salts (including isethionate)			
16	Thiomersal (INN)	0,007 % (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0,007 %	For eye make-up and eye make-up remover only	Contains thiomersal
17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds

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18	Undec-10-enoic acid and salts (*)	0,2 % (acid)	See Annex VI, Part 2, No 8	
19	Hexetidine (INN) (*)	0,1 %	[^{F12}]	
20	5-Bromo-5- nitro-1,3- dioxane	0,1 %	Rinse-off products only Avoid formation of nitrosamines [F8]	
21	Bronopol (INN) (*)	0,1 %	Avoid formation of nitrosamines	
22	2,4- Dichlorobenzyl alcohol (*)	0,15 %		
23	Triclocarban (INN) (*)	0,2 %	<1 ppm 3,3',4,4'-	oroazobenzene
24	4-Chloro-m-cresol (*)	0,2 %	Prohibited in the products intended to come into contact with mucous membranes	
25	Tricolosan (INN) (*)	0,3 %		
26	4-Chloro-3,5- xylenol (*)	0,5 %		
27	3,3'-Bis (1- hydroxymethyl-2, dioxoimidazolidin yl)-1,1'- methylenediurea ('Imidazolidinyl urea') (*)			
28	Poly (1- hexamethylenebig hydrochloride (*)	0,3 % uanide		

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

29	2- Phenoxyethanol (*)	1,0 %		
30	Hexamethylenetet (*) (methenamine) (INN)	r֎յդև∄ո&		
31	Methenamine 3- chloroallylochloric (INNM)	0,2 % de		
32	1-(4- Chlorophenoxy)-1 (imidazol-1- yl)-3,3- dimethylbutan-2- one (*)	0,5 %		
33	1,3-Bis (hydroxymethyl)-; dimethylimidazoli dione (*)			
34	Benzyl alchohol (*)	1,0 %		
35	1-Hydroxy-4- methyl-6(2,4,4- trimethylpentyl) 2-pyridon and its monoethanolamin salt (*)	1,0 % 0,5 % e	Products rinsed off For other products	
[F536	1,2- Dibromo-2,4- dicyanobutane (methyldibromo glutaronitrile)	0,1 %	Rinse-off products only]
37	6,6- Dibromo-4,4- dichloro2,2'- methylene- diphenol (Bromochloropher (*)	0,1 % n)		
38	4-Isopropyl-m- cresol	0,1 %		
39	Mixture of 5-Chloro-2- methyl-	[F20,0015 %](of a mixture in the ratio 3:1		1

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

	isothiazol-3(2H)- one and 2- methylisothiazol-3 one with magnesium chloride and magnesium nitrate	methylisothiazol	3	
[F1840	2-Benzyl-4- chlorophenol (clorophene)	0.2 %]
[^{F19} 41	2- Chloroacetamide	0,3 %		Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3 % expressed as clorhexidine		
43	1- Phenoxypropan-2- ol	1,0 %	Only for rinse- off products]
[^{F7} 44	Alkyl (C12- C22) trimethyl ammonium, bromide and chloride (*)	0,1 %		
45	4,4- dimethyl-1,3- oxizalidine	0,1 %	The pH of the finished product must not be lower than 6	
46	N- (Hydroxymethyl)- N- (dihydroxymethyl dioxo-2,5- imidazolidinyl-4)- N'- (hydroxymethyl) urea]
[F2247	1,6-Di (4- amidinophenoxy)- n-hexane (Hexamidine) and its salts (including	0,1 %]

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

	isethionate and p- hydroxybenzoate) (+)			
[F2448	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	1
[F2650	3-(p- chlorophenoxy)- propane-1,2 diol (chlorphenesin)	0,3 %		
51	Sodium hydroxymethylam acetate (Sodium Hydroxymethylgly			
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	1
[^{F30} 53	Benzethonium chloride	0,1 %	Rinse-off products only]
[^{F31} 54	Belzalkonium chloride, bromide and saccharinate (+)	0,1% calculated as benzalkonium chloride		Avoid contact with eyes]

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

[^{F34} 55	Benzylhemiformal	0,15 %	Only for products removed rinsing	s to be	
56	3-Iodo-2- propynylbutylcarb	0,05 % amate	1.	Not to be used for oral hygiene and lipcare products	
			2.	If the concentrin products intended to remain on the skin exceeds 0,02 % add the phrase: Contains iodine	

a Solely for products which might be used for children under three years of age and which remain in prolonged contact with

[F6PART 2 U.K.

LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
[F8]					
[^{F44}]					
[F8]					
[F39]					
[^{F8}]					

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

Textual Amendments

- **F44** Deleted by Commission Directive of 25 June 1996 (96/41/EC).
- **F45** Deleted by Commission Directive of 10 July 1995 (95/34/EC).
- **F46** Deleted by Commission Directive of 3 September 1998 (98/62/EC).
- **F47** Deleted by Commission Directive 2000/6/EC of 29 February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- **F48** Deleted by Commission Directive of 29 June 1994 (94/32/EC).

[F49ANNEX VII] U.K.

Textual Amendments

F49 Inserted by Council Directive of 26 October 1983 (83/574/EEC).

List of UV filters which cosmetic products may contain

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

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

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

PART 1 U.K. 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 ^a
[^{F50}]				
6	2- phenylbenzimidaz sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (texpressed as acid)		
[F247	3,3'-(1,4- Phenylenedimethy bis (7, 7- dimethyl-2- oxobicyclo-	acid)		1

a Not requiered if concentration is 0,5 % or less and when it is used only for product protection purposes.]

	[2,2,1]hept-1-yl-		
	methanesulfonic acid) and its salts		
[F238	1-(4-tert- butylphenyl)-3- (4- methoxyphenyl)pri dione	5 % ropane-1,3-]
[^{F24} 9	alpha-(2- Oxoborn-3- ylidene)- toluene-4- sulphonic acid and its salts	6 % (expressed as acid)	1
[F1310	2-cyano-3,3- diphenyl acrylic acid, 2- ethylhexyl ester (Octocrylene)	10 % (expressed as acid)	1
[^{F26} 11	Polymer of N- {(2 and 4)-[(2- oxoborn-3- ylidene)methyl]be	6 % nzyl}acrylamide]
[F3012	Octyl methoxycinnamate	10 % e]
[^{F31} 13	Ethoxylated Ethyl-4- Aminobenzoate (PEG-25 PABA)	10 %	
14	Isopentyl-4- methoxycinnamat (Isoamyl p- Methoxycinnamat		
15	2,4,6-Trianilino- (p-Carbo-2'- Ethylhexyl-1'Oxy Triazine (Octyl Triazone)	5 %)-1,3,5-	
16	Phenol,2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetramethyl-I-(Trimethylsilyl)OzDisiloxanyl)Propy		

Not requiered if concentration is 0,5 % or less and when it is used only for product protection purposes.]

	(Drometrizole Trisiloxane)			
17	Benzoic acid, 4,4-((6-(((1,1- dimethylethyl)ami 1,3,5- triazine-2,4- diyl)diimino)bis-,t (2- ethylhexyl)ester)	, , , ,	/l)amino)	
18	3-(4'- Methylbenxyliden d-1 camphor (4- Methylbenzyliden Camphor)			
19	3-Benzylidene camphor (3- Benzylidene Camphor)	2 %		
20	2-Ethylhexyl salicylate (Octyl- salicylate)	5 %		1
[^{F34} 21	4-Dimethyl- amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8 %		
22	2-Hydroxy-4- methoxybenzophe sulfonic acid (Benzophenone-5) and its sodium salt	5 % (of acid) none-5-		
23	2,2'-Methylene- bis-6-(2H- benzotriazol-2yl)- (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-	10 %		1

Not requiered if concentration is 0,5 % or less and when it is used only for product protection purposes.]

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	bis((4-(2-ethyl- hexyloxy)-2- hydroxy)- phenyl)-6-(4- methoxyphenyl)		
[F3226	Dimethicodiethylb (CAS No 207574-74-1)	od 0221 malonate	
27	Titanium dioxide	25 %]

a Not requiered if concentration is 0,5 % or less and when it is used only for product protection purposes.]

Textual Amendments

F50 Deleted by Commission Directive of 22 June 1993 (93/47/EEC).

[F20PART 2 U.K.

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

Reference number	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
[F33]					
[F46]					
[F33]					
[^{F47}]					
[F46]					
[^{F46}]					
[F25]					
[F33]					
[^{F47}]					
[^{F48}]					
[^{F46}]					
[^{F46}]					

[^{F48}]					
[^{F47}]					
[F50]					
[^{F46}]					
[^{F44}]]

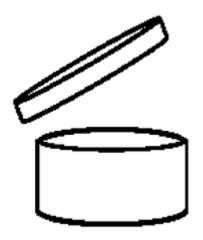
[F51ANNEX VIII] U.K.

Textual Amendments

F51 Inserted by Council Directive of 14 June 1993 (93/35/EEC).



[F35ANNEX VIIIa] U.K.



- (1) 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.
- (2) [F10OJ L 159, 29.6.1996, p. 1.]
- (3) $[^{\text{F27}}[^{\text{F28}}\text{OJ L }147, 31.5.2001, p. 1.]]$

Textual Amendments

- **F10** Substituted by Commission Directive 2002/34/EC of 15 April 2002 adapting to technical progress Annexes II, III and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).
- F27 Inserted by Commission Directive of 5 March 1998 (98/16/EC).
- **F28** Substituted by Commission Directive 2003/1/EC of 6 January 2003 adapting to technical progress Annex II to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).