

GOVERNMENT NOTICE GOEWERMENSKENNISGEWING

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 394

28 April 2006

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT NO 54 OF 1972)

REGULATIONS GOVERNING THE LABELLING, ADVERTISING AND COMPOSITION OF COSMETICS

The Minister of health intends, in terms of *section 15(1)* of the foodstuffs, cosmetics and Disinfectants Act, 1972 (*Ad No 54* of 1972), to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Inspectorate and Law Enforcement, within three months of the date of publication of this notice.

SCHEDULE

1. DEFINITIONS

In these regulations 'the Act' means the Foodstuffs, Cosmetic and Disinfectants *Ad, 1972 (Ad No 54* of 1972) and any expression to which a meaning has been assigned in the Act shall bear such meaning and, unless inconsistent with the context -

"address" means an address in the Republic of South Africa and the street or road number (if a number has been allotted), the name of the street or road and the name of the town, Village or suburb and, in the case of a farm, the name of the farm and of the magisterial district in which it is situated and, in the case of imported cosmetics, "address" means the address of the importer or distributor in the Republic;

"annex" means an annex to these regulations;

"bulk stock container" means a container that contains more than one unit of any specific cosmetic product;

"claim" in relation to a cosmetic, means any written, pictorial, visual or other descriptive matter or any verbal statement, communication, representation or reference which is brought to the attention of the public in any manner, including a trade name or brand name, and which refers to the characteristics of a product, in particular to its nature, identity, properties, composition, quality, durability, origin or method of manufacture or production;

"colourant" means any substance referred to in Annex III;

"immediate container" means a container which is in direct contact with the cosmetic;

"Ingredient" means any substance, including any cosmetic additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a cosmetic and which remains in the final product;

"indelible" means the information on the label should be legible throughout the period for which the product is used;

"legible" means that the labelling should be of sufficient size that it can be read by a person with normal vision at a distance of about 30 cm or by a person wearing normal corrective lenses without having to resort to aids such as magnification;

“**letter**” includes a digit;

“**main panel**” means the part of the label that bears the brand or trade name of the cosmetic in greatest prominence or any other part of the label that bears the brand or trade name in equal prominence;

“**name of the product**” in relation to a cosmetic, means a word or words which give a true description of the cosmetic and which can distinguish such cosmetic from other products it could be confused with;

“**outside container**” means a container which is not in direct contact with the cosmetic;

“**preservative**” means a substance which protects a cosmetic product against spoilage;

“**pressurised container**” means a container of metal, glass or plastic or a composition of these materials which contains liquids, powders or semisolids and a propellant and which discharges its contents under pressure through a valve system;

“**visible**” means the information on the **label** should not be obscured and should be seen without having to break open any component of packaging.

2. GENERAL

For the purposes of section 2(1) (a) (i), (ii) and (iii) of the Act, no person shall sell or manufacture or import for sale any cosmetic –

- (1) which has a substance listed in Annex I as an ingredient, unless the presence of such ingredient is in accordance with good manufacturing practice, technically unavoidable and not harmful or injurious to human health;
- (2) which contains a substance listed in column 2 of Annex II - Part I, Part 2 and part 3 – unless the corresponding restrictions, conditions of use and warnings which are to be printed on the label, as specified in columns 3, 4, 5 and 6 of the said Annex, are complied with;
- (3) which contains a *colourant* referred to in column 2 of Annex III – part 1 and Part 2 – unless such cosmetic is intended for application in accordance with the field of application referred to in columns 3, 4, 5 and 6 of the said Annex and subject to any limitations and requirements referred to in column 7 of the said Annex; except colorants not listed in the permitted annex as hair colorants only
- (4)
 - (a) which contains a preservative not listed in Annex V
 - (b) which contains a preservative listed in column 2 of Annex V – Part 1 and Part 2 – unless the corresponding maximum authorised concentration, limitation, requirements, conditions of use and warnings which are to be printed on the label, as specified in columns 4, 5 and 6 of the said Annex regarding such preservatives, are complied with;
 - (c) which contains an ultraviolet filter not listed in Annex VI;
 - (d) which contains an ultraviolet filter listed in column 2 of Annex VI – Part 1 and Part 2 – unless the corresponding maximum authorised concentration, limitations, requirements, conditions of use and warnings which are to be printed on the **label**, as specified in columns 4, 5 and 6 of the said Annex regarding such ultraviolet filter, are complied with.

3. IDENTIFICATION

No person shall sell or manufacture or import for sale any cosmetic, unless the cosmetic or its package, or the bulk stock from which it is taken, is labelled with the following information:

1. The immediate container of a cosmetic shall bear the following information:
 - (a) The name of the product
 - (b) The name of the manufacturer, packer, importer or seller or person on whose behalf the cosmetic is packed;
 - (c) The business address of the manufacturer, packer, importer or seller or person on whose behalf the cosmetic is packed: Provided that where it is not physically possible to provide this information on the immediate container, such information may be omitted;
 - (d) Warning statements where applicable

2. The outside container of a Cosmetic shall bear the following information:
 - (a) The name of the product
 - (b) The name and business address of the manufacturer, packer, importer or seller or person on whose behalf the cosmetic is packed;
 - (c) Warning statements where applicable
 - (d) List of ingredients as prescribed in Annexes II to VI.
 - (e) Particulars of precautions, including the precautions listed in Annexes II to VI.

3. where an unlabelled cosmetic is sold from a bulk stock container, such bulk stock container shall be labelled in accordance with the requirements of subregulation 3(2) of these regulations, and the label shall also state special storage conditions where applicable.

4. LANGUAGE

Unless expressly otherwise provided in regulations published in terms of the Act, the information required to appear on a label shall be in at least one of the official languages of the Republic of South Africa.

5. PRESENTATION

Information required to appear on a label shall be visible, legible and indelible and the legibility thereof shall not be obstructed by pictorial or any other matter, printed or otherwise.

6. WARNING STATEMENTS

Deodorants or anti-perspirant products

- (1) The label of a deodorant or anti-perspirant product which contains ingredients listed in Annex II shall contain the following warning: "CAUTION – do not apply to sore or damaged skin. Discontinue use if rash develops."

Products packed in pressurised containers

- (2) The label of any cosmetic product in any pressurised container shall contain the following statements: "WARNING – PRESSURISED – Protect from sunlight and exposure to temperatures exceeding 50°C. Do not pierce or burn, even after use."

7. ADVERTISING

No person shall advertise a cosmetic in an advertisement which contains any information, claim, reference or performance explanation which is not allowed on the label of a cosmetic in terms of these regulations.

8. SPECIAL PROVISIONS

Names of ingredients

- (1) The names used for ingredients on a label shall correspond with those used in Annexes, or in the International Cosmetics Ingredients Dictionary (ICID). If an ingredient is not described in the aforementioned publication, the description thereof in the United States Pharmacopoeia (USP), the British Pharmacopoeia (BP) or the European Pharmacopoeia (EP) shall be used.

9. REPEAL

Government Notice No. R. 908 of 27 May 1977, as amended by Government Notices Nos R. 1389 of 22 July 1977, R. 1843 of 28 August 1981, R. 2298 of 26 October 1984 and R. 2567 of 15 November 1985, and Government Notice No. R. 1227 of 24 June 1988, as amended by Government Notices Nos. R. 1783 of 2 September 1988 and R. 1861 of 10 August 1990, are hereby repealed in so far as they relate to cosmetics.

ANNEX I

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS

The alphabetical list set out in column 2 of this Annex contains one or more of the names of each of the substances not allowed in cosmetic products. In certain cases a name is given for a group of substances, the names of particular examples of which are also given, and in such a case all substances comprised in the group are included, whether or not more specifically named.

The numbers given in columns 1, 3 and 4 are for information only.

Those in column 3 are cross-references to other names listed for the same substances (except where a name is that of a group of substances, the cross-references are to particular examples of that group, and any cross-reference in parenthesis is to the name of a group of substances within which the particular substance falls).

Those in column 4 are cross-references to Annex II of the original EU Directive, from **which** this Annex is derived.

ANNEX I

LIST OF SUBSTANCES WHICH MUST NOT FORM PART
OF THE COMPOSITION OF COSMETIC PRODUCTS

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
1	Acenocoumarol (INN)	397	254
2	Acetonitrile		393
3	3-(a-Acetylbenzyl)-4-hydrocoumarin and its salts	399,761	203
4	b-Acetoxyethyl trimethyl ammonium hydroxide and its salts	6	2
5	2-Acetylamino-5-chlorobenzoxazole	165	1
6	Acetylcholine and its salts	4	2
7	Acetylene chlorides	250,758	126
8	Acetylenic alcohols, their esters, ethers and salts	17	16
9	Acetyl ethyl tetramethyl tetralin (AETT)	342, 698a	362
10	7a-Acetylthio-3-oxopregn-4-ene-17a, 17propionolactone	650	4
11	Aconitine (principal alkaloid of <i>Aconitum napellus L.</i>) and its salts	-	12
12	<i>Aconitum napellus L.</i> leaves, roots and galenical preparations	-	11
13	<i>Adonis vernalis L.</i> and its preparations		13
14	Adrenaline	270,315	14
14a	Alanroot oil (<i>Inula helenium</i>) (CAS No. 97676-35-2) when used as a fragrance ingredient		423
15	Alkali pentacyanonitrosylferrate(2-)	603,645	255
16	o-Alkyldithiocarbonic acids, salts of	762	336
17	Alkyne alcohols, their esters, ethers and salts	8	16
18	Alloclamide (INN) and its salts	22	19
19	Allyl isothiocyanate		18
20	2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts		224
21	N-Allylnormorphine, its salts and ethers	493	20

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-referenc to Annex II of the original EU Directive
22	2-Allyloxy-4-chloro-N-[2-(diethylamino)-ethyl] benzamide and its salts	18	19
23	Alypine and its salts	45,110	143
24	Amibenonium chloride (INN)	(528)	132
25	Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex VII.		167
26	2-Amino-1,2-bis(4-methoxyphenyl) ethanol and its salts		29
27	Aminocaproic acid (INN) and its salts	31	7
28	2-Amino-5-chlorobenzoxazole	768	24
29	4-Amino-N-(2-diethylaminoethyl)benzamide , its salts and derivatives	608	25
30	Aminoheptane, its isomers and Salts	749	27
31	6-Aminohexanoic acid and its salts	27	7
32	a-(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	518	257
33	4-Amino-N10-methylfolic acid	453	6
34	2-Amino-6-methylheptane and its salts	288,524	28
35	2-Amino-4-methylhexane and its salts	289,472	30
36	2-Amino-4-nitrophenol	-	383
37	2-Amino-5-nitrophenol		384
38	4-Amino-2-nitrophenol	-	412
39	4-Aminosalicylic acid and its salts	-	31
40	Aminotoluenes , their isomers, salts and halogenated and sulphonated derivatives	717	32
41	Aminoxylenes , their isomers, salts and halogenated and sulphonated derivatives	764	33
42	Amitriptyline (INN) and its salts	284	146
43	<i>Ammi majus</i> and its galenical preparations	-	35
44	Amphetamine (INN), its salts and derivatives and salts of those derivatives	(679)	21

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original Directive
45	Amydracaine and its salts	23,110	143
46	Amylene chloride	251	36
47	Amyl 4-dimethylaminobenzoate, mixed isomers	533	381
48	Amyl nitrites	-	247
49	Amylobarbitone and its salts	(70)	220
50	Amylocaine and its salts	282	50
51	<i>Anamirta cocculus L.</i> (fruit)	-	106
52	Substances with androgenic effect	-	37
53	Aniline, its salts and halogenated and sulphonated derivatives	-	22
54	Anthracene oil	-	38
55	Anti-androgens with steroid structure	-	390
56	Antibiotics	-	39
57	Antimony and its compounds	-	40
58	<i>Apocynum cannabinum L.</i> and its preparations	-	41
59	Apomorphine and its salts	695	42
60	Apronalide	420	216
61	Arecoline	483	238
62	Aristolochic acid and its salts; <i>Aristolochia spp.</i> and their preparations	-	365
63	Arsenic and its compounds	-	43
64	(Omitted)	-	-
65	<i>Atropa belladonna L.</i> and its preparations	-	44
66	Atropine, its salts and derivatives	-	45
67	Azacyclonol (INN) and its salts	305	286
68	Azamethonium bromide (INN)	(474)	121
69	Barbitone and its salts	(70)	220
70	Barbiturates	546, 557, 630, 640, 707	220

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
71	Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, and lakes, salts and pigments prepared from the colouring agents listed with the reference (3) in Annex IV.	-	46
72	Bemegride (INN) and its salts	337,338	183
73	Benactyzine (INN)	258	157
74	Bendrofluazide and its derivatives	75, 91	53
75	Bendroflumethiazide (INN) and its derivatives	74, 91	53
75a	Benzodiazepines	78	49
76	Benzamine and its salts	742	51
77	Benzatropine (INN) and its salts	301	158
78	Benzazepines, their salts and derivatives	75a	49
79	Benzene	-	47
80	Benzene-1,2-diol	154, 628	408
81	Benzene-1,2,3-triol	629	409
82	(Omitted)		
83	2-Benzhydroxyethyl dimethylamine and its salts	296	339
84	Benzidine	243	26
85	Benzilium bromide (INN)	96	60
86	2-Benziloyloxymethyl-1,1-dimethylpyrrolidinium methyl sulphate	600	239
87	Benzimidazolone	88,267	48
88	Benzimidazol-2(3H)-one	87,267	48
89	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol, except for normal content in natural essences used.	212	357
90	(Omitted)		
91	Benzothiadiazine and its derivatives	74, 75	53
92a	Benzyl cyanide (CAS No. 140-29-41, when used as a fragrance ingredient)	-	424

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to <i>this</i> Annex	(4) Cross-reference to Annex II of the original EU Directive
93	(Omitted)		
94	3-(N-Benzylhydrazinocarbonyl)-5-methylisoxazole	415	52
95	Benzylideneacetone	565	356
96	3-Benzylloxy-1,1-diethylpyrrolidine hydrobromide	85	60
97	4-Benzylloxyphenol	(323), 459	178
98	2-[Benzyl-N-(2-pyridyl)amino]-ethyl dimethylamine	624,746	347
99	Bergapten(e) (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
100	Beryllium and its compounds	-	54
101	Betamethasone (INN)	(361)	300
102	Betoxycaine (INN) and its salts	257	23
103	BHC (ISO) (<i>gamma</i> -BHC)	429,370,372	195
104	Bietamiverine (INN)	261	287
105	1,6-Bis(2-chloroethylamino)-1,6-dideoxy-mannitol and its salts	437	89
106	2-[Bis(2-chloroethyl)amino]-1-oxa-3-aza-2-phosphacyclohexane-2-oxide and its salts	109,231	88
107	N,N-Bis(2-chloroethyl)methylamine and its salts	161,491	87
108	N,N-Bis(2-chloroethyl)methylamine-N-oxide and its salts	492	86
109	N,N-Bis(2-chloroethyl)-1,3,2-oxaza-phosphinan-2-ylamine-P-oxide and its salts	106,231'	88
110	1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts	23, 45	143
111	Bis(hydroxyalkyl)amines, not further N-substituted	255,274,641	411
112	2,2-Bis(hydroxymethyl)butan-1-ol trinitrate	614	206
113	2,6-Bis(β -hydroxyphenethyl)-1-methylpiperidine and its salts	431	219
114	3,3-Bis(4-hydroxyphenyl)phthalide	558	417
115	Bis(8-hydroxyquinolinium)sulphate, except for the uses provided for in entry number 51 in Annex III, Part 1.	(401, 532)	395

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
116	Bithionol (INN)	706	352
117	Bretyliumtosilate (INN) (Bretylium tosylate)	120	56
118	Bromine, elemental	-	55
119	Bromisoval (INN)	122	58
120	<i>p</i> -Bromobenzylethylidimethylammonium <i>p</i> -toluenesulphonate	117	56
121	2-Bromo-2-ethylbutylrylurea	150	57
122	2-Bromo-3-methylbutylrylurea	119	58
123	1- <i>p</i> -Bromophenyl-1-(2-pyridyl)-3-dimethylaminopropane and its salts	124	59
124	Brompheniramine (INN) and its salts	123	59
125	Brucine	-	62
126	Butanilicaine (INN) and its salts	467	90
127	Butobarbione and its salts	(70)	220
128	Butopiprine (INN) and its salts	130	288
129	2-Butoxy- <i>N</i> -(2-diethylaminoethyl)-cinchoninamide and its salts	192	129
130	2-Butoxyethyl phenyl(piperidino)acetate and its salts	128	288
131	1-Butyl-3-(<i>N</i> -crotonoylsulphanilyl) urea	-	108
132	4-Butyl-1,2-diphenylpyrazolidine-3,5-dione	564	67
133	4- <i>tert</i> -Butyl-3-methoxy-2,6-dinitrotoluene	490	414
134	4-Butyl-1-phenylpyrazolidine-3,5-dione	487	64
135	1-Butyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	716	65
136	1-Butyl-3-sulphanilylurea	151	66
137	4-Butylthiobenzhydriyl 2-(dimethylamino) ethyl sulphide	144	140
137a	5- <i>tert</i> -Butyl-1,2,3-trimethyl-4,6-dinitrobenzene		422
138	Cadmium and its components	-	68
139	Calabar bean	586	281
140	Calciferol	317, (760)	335

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
141	Cantharides, <i>Cantharisvesicatoria</i>	648	69
142	Cantharidin	379	70
143	Captan (ISO)	735	370
144	Captodiame (INN)	137	140
145	Caramiphen (INN) and its salts	568	169
146	<i>N</i> -(3-Carbamoyl-3,3-diphenylpropyl)- <i>N,N</i> -diisopropylmethylammonium salts	419	156
147	Carbazole, nitroderivatives or	509	72
148	Carbon disulphide	-	73
149	Carbon tetrachloride	691	315
150	Carbromal (INN)	121	57
151	Carbutamide (INN)	136	66
152	Carisoprodol (INN)	481	235
153	Catalase		74
154	Catechol	80,628	408
155	Cells, tissues or products of human origin		416
156	Cephaeline and its salts		75
157	<i>Chenopodiumambrosioides</i> (essential oil)		76
158	Cherry laurel water	619	291
159	Choral hydrate	733	77
160	Chlorine		78
161	Chlormethine (INN) and its salts	107,491	87
162	Chloromezanone (INN)	176	91
163	4-Chlorobenzene-1,3-disulfonamide	195	85
164	5-Chloro-1,3-benzoxazol-2(3H)-one	187	82
165	<i>N</i> -5-Chlorobenzoxazol-2-ylacetamide	5	■
166	2-Chloro-6-methylpyrimidin-4-yl dimethylamine	170,217	83

(1) Number in #is Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
167	2-Chloro-9-[3-dimethylamino]propylidene]thioxanthene (cis-form) and its salts	184	84
168	Chloroethane	328	96
169	Chloroform	734	366
170	2-Chloro-6-methylpyrimidin-4-ylidene thylamine	166,217	83
171	Chlorophacinone(ISO)	177	93
172	1-(p-Chloro-a-phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	402	240
173	2-(4-Chlorophenyl)-1-[4-(2-diethylaminoethoxy)phenyl]-1-p-tyloethanol	745	92
174	4-[4-(4-Chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	369	185
175	2-(4-Chlorophenyl)-3-methylbutane-2,3-diol	552	95
176	2-(4-Chlorophenyl)-3-methyl-1,3-thiazinan-4-one 1,1-dioxide	162	91
177	2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan-1,3-dione	171	93
178	2-[1-(4-Chlorophenyl)-1-phenylethoxy]ethyl-(dimethyl)amine	181	94
179	Chloropicrine	736	325
180	3-(4-Chloro-3-sulphamoylphenyl)-3-184 , hydroxyisoindolin-1-one	186	262
181	Chlorphenoxamine (INN)	178	94
182	Chlorpromazine (INN)	(559)	320
183	Chlorpropamide (INN)	615	79
184	Chlorprothixene (INN) and its salts	167	84
185	Chlorthalidone (INN)	180,186	262
186	Chlorthalidone	180,185	262
187	Chlorzoxazone (INN)	164	82
188	Cholecalciferol	(760)	335
189	Choline salts and their esters e.g. choline chloride	-	168
190	Chromium, chromic acid and its salts	-	97
191	Chrysoidine citrate hydrochloride	563	81
192	Cinchocaine (INN) and its salts	129	129

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
193	Cinchophen (INN), its salts and derivatives and salts of these derivatives	578	8
194	<i>Claviceps purpurea Tul.</i> , its alkaloids and galenical preparations	318	98
195	Clofenamide (INN)	163	85
196	Clofenotane (INN)	233,732	123
197	Cobalt benzenesulphonate		101
198	Cocculin	590	282
199	Colchicine, its salts and derivatives	-	102
200	Colchicoside and its derivatives		103
201	<i>Colchicum autumnale L.</i> and its galenical preparations		104
202	Colouring agent CI 12075 and its lakes, pigments and salts	-	397
203	Colouring agent CI 12140		378
204	Colouring agent CI 13065		387
205	Colouring agent CI 15585	-	401
206	Colouring agent CI 26105		379
207	Colouring agent CI 42535	-	388
208	Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2	-	380
209	Colouring agent CI 42640	-	386
210	Colouring agent CI 61554		389
211	Colouring agents CI 45170 and CI 45170:1	-	398
212	Coniferyl benzoate (except natural content of essences)	89	357
213	Coniine	616	290
214	<i>Conium maculatum L.</i> (fruit, powder galenical preparations)		99
215	Convallatoxin		105
215a	Costus root oil	637a	1133
216	Coumetarol (INN)	454	225

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
217	Crimidine (ISO)	165,169	83
278	Croton <i>tiglium</i> (oil)	-	107
218a	Crude and refined coal tars		420
219	Curare and curarine	-	109
220	Curarizants, synthetic	-	110
221	1-(3-Cyano-3,3-diphenylpropyl)-4-ethoxycarbonyl-4-phenylpiperidinium chloride	297	80
221a	Cyclamen alcohol (CAS No. 4756-19-8), when used as a fragrance ingredient		425
222	Cyclarbamate (INN)	230	122
223	Cyclizine (†) and its salts	302	159
224	Cyclobarbitone and its salts	(70)	220
225	Cyclocoumarol	268	234
226	2- α -Cyclohexylbenzyl(<i>N,N,N',N'</i> -tetraethyl)trimethylenediamine	553	112
227	2-Cyclohexyl-3,5-dimethylphenol and its salts	229	113
228	1-Cyclohexyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	364	100
229	Cyclomenol (INN) and its salts	227	113
230	Cyclopentane-1,1-dimethanol dicarbanilate	222	122
231	Cyclophosphamide (INN) and its salts	106,109	88
232	Datura <i>stramonium</i> L. and its galenical preparations	652	301
233	DDT (ISO) (<i>pp'</i> -DDT)	198,732	123
234	Deanol aceglumate (INN)	279	3
235	Decamethonium bromide (INN)	(236)	214
236	Decamethylenebis (trimethylammonium) salts	235	214
237	Dextromethorphan (INN) and its salts	458	226
238	Dextropropoxyphene (INN)	281	116
239	<i>O,O</i> -Diacetyl- <i>N</i> -allyl- <i>N</i> -normorphine	-	117
240	2,4-Diaminoanisole (CI 76050) and its salts	456, 462	376

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
241	2,5-Diaminoanisole and its salts	457,461	377
242	1,2-Diaminobenzene and its salts	571	363
243	<i>p,p'</i> -Diaminodiphenyl	84	26
244	2,4-Diaminophenylethanol and its Salts		407
245	1,4:3,6-Dianhydrosorbitol 2,5-dinitrate	422	148
246	5-(α,β -Dibromophenethyl)-5-methylhydantoin	-	119
247	Dibromosalicylanilides	248,444	351
248	Dibromsalan (INN)	(247)	351
249	Dichloroethanes	330,335	125
250	Dichloroethylenes	7,758	126
251	2,3-Dichloro-2-methylbutane	46	36
252	Dichlorosalicylanilides		349
253	Dicoumarin	254,470	231
254	Dicoumarol (INN)	253,470	231
255	Diethanolamine	(111,641)	41 ■
256	2-(Diethylaminoethoxy)ethyl-phenylpiperidine-1-acetate dimethiodide	599	137
257	2-Diethylaminoethyl 3-amino-4-butoxybenzoate and its salts	102	23
258	2-Diethylaminoethylbenzilate	73	157
259	2-Diethylaminoethyl 4-ethoxybenzoate and its salts	411,537	179
260	2-diethyl aminoethyl 3-hydroxy-dphenylbenzoate and its salts		128
261	2-Diethylaminoethylphenyl(piperidino) acetate	104	287
262	3-Diethylaminopropylcinnamate		130
262a	Diethyl maleate (CAS No. 141-05-9) when used as a fragrance ingredient		426
263	Diethyl 4-nitrophenyl phosphate	535	170
264	O,O-Diethyl O-4-nitrophenyl phosphorothioate	536	131
265	Difenclozazine (INN)	567	270

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
266	Digitaline and all heterosides of <i>Digitalis purpurea L.</i>	-	134
267	4,5 Dihydrobenzimidazol-4-one	87, 88	48
267a	Dihydrocoumanne (CAS No. 119-84-6) when used as a fragrance ingredient	-	427
268	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H-5H-pyrano[3,2-c][1]-benzopyran-5-one	225	234
269	Dihyrotachysterol (INN)	-	342
270	3,4-Dihydro- α -(methylaminomethyl)benzyl alcohol	14,315	14
270a	2,4-Dihydroxy-3-methylbenzaldehyde (CAS No. 6248-20-0) when used as a fragrance ingredient	-	428
271	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin		207
272	1-(3,4-Dihydroxyphenyl)-2-ethylamino-propan-1-ol and its salts	294	136
273	1-(3,4-Dihydroxyphenyl)-2-(4-isopropylamino)ethanol	418	17
274	Diisopropanolamine	(111,641)	411
275	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodite	413	361
276	Dimethoxane	286	368
277	4-[2-(3,4-Dimethoxyphenyl)ethyl]-1-(2-chlorophenyl)piperazine and its salts	439	141
278	Dimethylamine	-	42
279	2-Dimethylaminoethyl <i>N</i> -acetylglutamate	234	3
280	2-Dimethylaminoethyl <i>p</i> -butylaminobenzoate and its salts	688	63
281	(+)-4-Dimethylamino-3-methyl-1,2-diphenyl-2-propionyloxybutane	238	116
282	1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts	50	50
283	2-Dimethylaminopropiophenone and its salts	446	145
284	3-(3-Dimethylaminopropylidene)-1,2,4,5-dibenzocyclohepta-1,4-diene and its salts	42	146
285	1-Dimethylbiguanide and its salts	448	147
285a	Dimethylcitrate (CAS No. 617-54-9) when used as a fragrance ingredient	-	431
286	2,6-Dimethyl-1,3-dioxan-4-yl acetate	276	368

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
286a	7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No. 26651-96-7) when used as a fragrance ingredient	-	432
287	Dimethylformamide		355
288	1,5-Dimethylhexylamine and its salts	34,524	28
288a	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No. 40607-48-5) when used as a fragrance ingredient	-	429
289	3-Dimethylpentylamine and its salts	35,472	30
290	Dimethyl sulfoxide (INN)	-	338
290a	4,6-Dimethyl-8-tert-butylcoumarin (CAS No. 17874-34-9) when used as a fragrance ingredient		430
290b	6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No. 141-10-6) when used as a fragrance ingredient	-	433
291	Dimevamide (INN) and its salts	298	153
292	Dinitrophenol isomers	-	151
292a	Diphenylamine (CAS No. 122-39-4) when used as a fragrance ingredient	-	434
293	Dioxane	-	343
294	Dioxethedrin (INN) and its salts	272	136
295	2,5-Dioxo-3,3-diethyl-5-methylpiperidine and its salts	484	733
296	Diphenhydramine (INN) and its salts	83	339
297	Diphenoxylate hydrochloride (INN)	221	80
298	2,2-Diphenyl-4-dimethylaminovaleramide and its salts	291	153
299	5,5-Diphenyl-4-imidazolidone	-	160
300	4-Diphenylmethoxy-1-methylpiperidine and its salts	306	154
301	3-Diphenylmethoxytropene and its salts	77	158
302	1-Diphenylmethyl-4-methylpiperazine and its salts	223	159
303	1,2-Diphenyl-4-(2-phenylsulphinyloethyl)-pyrazolidine-3,5-dione	662	155
304	a,a-Diphenyl-2-piperidinemethanol and its salts	598	285
305	a,a-Diphenyl-4-piperidinemethanol and its salts	67	286

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
306	Diphenylpyraline (INN) and its salts	300	154
307	2,5-Dipropoxy-3,6-bis(ethyleneimino)-1,4-benzoquinone	410	152
308	4-Dipropylsulphamoylbenzoicacid	607	161
309	Disulfiram (INN)	700,711	162
310	Dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) - (pyrithione disulphide + magnesiumsulphate)	626	396
311	Doxylamine (INN) and its salts	577	176
312	Emetine, is salts and derivatives	-	163
313	Endrin (ISO)	373	196
314	Ephedrine and its salts	-	164
315	Epinephrine (INN)	14,270	14
316	1,2-Epoxybutane	-	400
317	Ergocalciferol (INN)	140, (760)	335
318	Ergot and its alkaloids	194	98
319	Eserine and its salts	587	166
320	Ethionamide (INN)	336	319
321	Ethoheptazine (INN) and its salts	477	173
322	Ethopropazine (INN) and its salts	(559)	320
322a	7-Ethoxy-4-methylcoumarin		1134
323	4-Ethoxyphenol	97,459	178
324	4-Ethoxy-m-phenylenediamine and its salts	-	406
324a	Ethyl acrylate (CAS No. 140-88-5) when used as a fragrance ingredient	-	435
325	2-Ethylamino-5-phenyloxazolin-4-one	345	180
326	Ethyl bis (4-hydroxycoumarinyl)acetate and salts of the acid	327	204
327	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	326	204
328	Ethyl chloride	168	96
329	Ethyl 1,3-dimethyl-4-phenylazepane-4-carboxylate and its salts	447	171

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
330	Ethylene chlorides	(249)	125
331	Ethylene oxide		182
332	2-Ethyl-2,3-epoxyhexamide and its derivatives	529	165
333	Ethyl p-fluorophenyl sulphone	348	189
334	Ethyl 1-(2-hydroxy-2-phenylethyl)-4-phenylpiperidine-4-carboxylate and its salts	531	172
335	Ethyfidenedichloride	(249)	125
336	3-Ethylisothionicotinamide	320	319
337	3-Ethyl-3-methylglutarimide and its salts	72,338	183
338	4-Ethyl-4-methylpiperidine-2,6-dione and its salts	72,337	183
339	2-Ethyl-3-methylvaleramide	754	184
340	Ethylphenacemide	554,566	272
341	2-Ethyl-2-phenylglutarimide and its salts	362	181
342	3'-Ethyl-5',6',7,8'-tetrahydro-5',6',8',8'-tetramethyl-2'-acetonaphthone	9	362
343	Ethyl urocanate	(406)	418
344	Fenadiazole (INN)	527	208
345	Fenzolone (INN)	325	180
346	Fenyramidol (INN)	576,580	274
346a	Fig Leaf absolute (<i>ficus Carica</i>) (CAS No. 68916-52-9) when used as a fragrance ingredient	-	436
347	Fluanisone (INN)	351	187
348	Fluoresone (INN)	333	189
349	4'-Fluoro-4-[4-hydroxy-4-(a,a,a-trifluoro-m-tolyl)piperino]butyrophenone	739	188
350	6-Fluoro-16-methyl-1 β ,17a,21-trihydroxypregna-1,4-diene-3,20-dione	534	186
351	1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)-1-piperaziny]butan-1-one	347	187
352	5-Fluoropyrimidine-2,4-dione	353	190
353	Fluorouracil (INN)	352	190

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) cross-reference to Annex II of the original EU Directive
354	Fluphenazine (INN)	(559)	320
355	Furazolidone (INN)	512	252
356	Furfuryltrimethylammoniumsalts	358	192
357	Furocoumarines (e.g. trioxysalan, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1mg/kg	99, 463, 621, 744	358
358	Furtrethoniumiodide (INN)	(356)	192
350	Galantamine (INN)	-	193
360	Gallamine triethiodide (INN)	517	320
361	Glucocorticoids	101	300
362	Glutethimide (INN) and its salts	341	181
363	Glycerol trinitrate	513,613	253
364	Glycyclamide (INN)	228	100
365	Gold salts	-	296
366	Guaifenesin (INN)	460	230
367	Guanethidine (INN) and its salts	368	259
368	<i>N</i> -(2-Guanidinoethyl)azocane and its salts	367	259
369	Haloperidol (INN)	174	185
370	HCH (ISO) (gamma-HCH)	103,372,429	195
371	HETP	378	316
372	1,2,3,4,5,6-Hexachlorocyclohexane	103,370,429	195
373	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i>)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene	313	196
374	Hexachloroethane	-	197
375	3,3',4,4',6,6'-Hexachloro-2,2'-methylenediphenol	376	371
376	Hexachlorophene (INN)	37s	371
377	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i>)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene	416	198

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
378	Hexaethyltetraphosphate	371	316
378a	Hexahydrocoumarin		1135
379	(<i>R,R</i> ,2 <i>S</i>)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride	142	70
380	(3 <i>S</i> ,5 <i>aR</i> ,9 <i>bS</i>)-3,3 <i>a</i> ,4,5,5 <i>a</i> ,9 <i>b</i> -Hexahydro-3,5 <i>a</i> ,9-trimethylnaphto[1,2- <i>b</i>]furan-2,8-dione	637	217
381	Hexamethonium bromide (INN)	(382)	124
382	Hexamethylenebis(trimethylammonium) salts	381	124
383	Hexapropymate (INN)	617	115
384	Hydrastine, hydrastinine and their salts		199
385	Hydrazides and their salts	-	200
386	Hydrazine, its derivatives and their salts	-	201
387	2-Hydrazino-octane and its salts	522	202
387a	Hydroabietyl alcohol (CAS No. 13393-93-6) when used as a fragrance ingredient	-	440
388	Hydrocyanic acid and its salts	390, 409, 602, 643	111
389	Hydrofluoric acid and its normal salts , its complexes and hydrofluorides (except those given in Annex III, Part 1)	-	191
390	Hydrogen cyanide and its salts	388, 409, 602, 643	111
391	Hydroquinone and its monobenzyl, monoethyl, and monomethyl ethers	-	-
392	7-[2-Hydroxy-3-(2-hydroxyethyl- <i>N</i> -methylamino)propyl]theophylline	763	135
393	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts	740	5
394	3-[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propionic acid and its salts	714	9
395	2-Hydroxy-3-(2-methoxyphenyl) propylcarbamate	451	205
396	1-Hydroxymethyl-1-cyclohexylacetic acid, sodium salt	644	114
397	4-Hydroxy-3-[4-nitrophenyl]-3-oxobutyl coumarin	1	254
398	8-Hydroxy-5-nitroquinoline and its salts	516	209
399	4-Hydroxy-3-(3-oxo-1-phenylbutyl) coumarin and its salts	3,761	203
400	11 <i>a</i> -Hydroxypregn-4-ene-3,20-dione and its esters		385

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
401	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in no. 51 of Annex III	15,532,631	395
402	Hydroxyzine (INN)	172	240
403	Hyoscine, its salts and derivatives	639	295
404	Hyoscyamine, its salts and derivatives	-	210
405	<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	-	211
406	3-Imidazol-4-ylacrylic acid and its ethyl ester	343,752	418
407	2-Imino-5-phenyloxazolidin-4-one and its salts	539	212
408	Imperatorin	466	34
409	Inorganic cyanides	(388, 390), 602, 643	III
410	Inproquone (INN)	307	152
411	Intracaine and its salts	259,537	179
412	Iodine	-	213
413	Iodothymol	275	361
414	Ipecacuanha (<i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	-	215
415	Isocarboxazide (INN)	94	52
416	Isodrin (ISO)	377	198
417	Isometheptene (INN) and its salts	464	228
418	Isoprenaline (INN)	273,421	17
419	isopropamide iodide (INN)	(146)	156
419a	6-Isopropyl-2-decahydronaphthalenol (CAS No. 34131-99-2) when used as a fragrance ingredient	-	441
420	(2-Isopropylpent-4-enoyl)urea	60	216
421	Isoproterenol	273,410	17
422	Isosorbide dinitrate (INN)	245	148
423	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)		294
424	Laurel oil	425	359

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
425	<i>Laurus nobilis</i> L. (oil from seeds)	424	359
426	Lead and its compounds		289
427	Levopropacetoperane and its salts	595	284
428	Lidocaine (INN) (Lignocaine)	-	399
429	Lindane	103,370,372	195
430	<i>Lobelia inflata</i> L. and its galenical preparations	-	218
431	Lobeline (INN) and its salts	113	219
432	LSD	(434.435)	127
433	Lupinidine and its salts	649	299
434	Lysergic acid diethylamide and its salts	432,435	127
435	Lysergide (INN) and its salts	432,434	127
436	Malononitrile	-	149
437	Mannomustine (INN) and its salts	105	89
438	Mecamylamine (INN)	699	229
439	Mefeclozazine (INN) and its salts	277	141
440	Mephenesin (INN) and its esters	719	322
441	Meproamate (INN)	482	236
442	Mercury and its compounds, except those listed in Annex VI	-	221
443	Mescaline and its salts	741	222
444	Metabromsalan (INN)	(247)	351
445	Metaldehyde	601	223
446	Metamfepramone (INN) and its salts	283	145
447	Metethoheptazine (INN) and its salts	329	171
448	Metformin (INN) and its salts	285	147
449	Methapyriline (INN) and its salts	625	144
450	Metheptazine (INN) and its salts	469	174

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
451	Methocarbamol (INN)	395	205
452	Methohexitone and its salts	(70)	220
453	Methotrexate (INN)	33	6
454	2-[4-Methoxybenzyl-N-(2-pyridyl)amino]-ethylidimethylamine maleate	623	346
455	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	216	225
455a	7-Methoxycoumarin (CAS No. 531-59-9) when used as a fragrance ingredient	-	442
456	1-Methoxy-2,4-diaminobenzene and its salts	240,462	376
457	1-Methoxy-2,5-diaminobenzene and its salts	241,461	377
458	(+)-3-Methoxy-N-methylmorphinan and its salts	237	226
459	4-Methoxyphenol	97,323	178
460	3-(2-Methoxyphenoxy)propane-1,2-diol	366	230
460a	4-(4-Methoxy phenyl-3-butene-2-one (CAS No. 943-88-4) when used as a fragrance ingredient	-	443
461	2-Methoxy-p-phenylenediamine and its salts	241,457	377
462	4-Methoxy-m-phenylenediamine and its salts	240, 456	376
462a	1-(4-Methoxyphenyl)-1-penten-3-one (CAS No. 104-27-8) when used as a fragrance ingredient	-	444
463	Methoxypsoralen (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
464	6-Methylamino-2-methylhept-2-ene and its salts	417	228
465	2-Methyl-1,2-bis(3-pyridyl)propan-1-one	485	292
466	9-(3-Methoxybut-2-enyloxy)furo-[3,2-g]chromen-7-one	408	34
467	2-Methyl-6-chloroanilide of n-butylaminoacetic acid and its salts	126	90
467a	7-Methylcoumarin (CAS No. 2445-83-2) when used as a fragrance ingredient	-	446
468	1-Methyl-2,4-diaminobenzene and its salts	478	364
469	Methyl 1,2-dimethyl-4-phenylazepane-4-carboxylate and its salts	450	174
470	3,3-Methylenebis-(4-hydroxycoumarin)	253,254	231

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
470a	Methyleugenol (CAS No. 93-15-2) except for normal content in the natural natural essences used and provided that the concentration does not exceed: * 0.01% in fine fragrance * 0.004% in eau de toilette * 0.002% in fragrance cream * 0.001% in rinse-off products * 0.0002% in other leave-on products and oral hygiene products	-	451
471	2-Methylheptylamine and its salts	-	227
471a	5-Methyl-2,3-hexanedione (CAS No. 13706-86-0) when used as a fragrance ingredient	-	447
472	4-Methyl-2-hexylamine and its salts	35,289	30
473	1-Methylimidazole-2-thiol	475,705	233
474	<i>N,N'</i>-(Methylimino)diethylene[bis(ethyl-dimethylammonium)] salts	68	121
475	1-Methyl-2-mercaptoimidazole	473,705	233
476	Methylphenidate (INN) and its salts	573	175
477	1-Methyl-4-phenyl-4-carbethoxyhexamethyleneimine and its salts	321	173
478	4-Methyl-m-phenylenediamine and its salts	468	364
479	2-Methyl-m-phenylenediamine	-	413
480	3-Methyl-2-phenylmorpholine, its derivatives and salts	556	232
481	2-Methyl-2-propyl-1-isopropylcarbamoyloxy-3-carbamoyloxypropane	152	235
482	2-Methyl-2-propyltrimethylene dicarbamate	441	236
483	<i>N</i> -Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester	61	238
483a	Methyl <i>trans</i> -2-butenoate (CAS No. 623-43-8) when used as a fragrance ingredient	-	445
484	Methyprylon (INN) and its salts	295	133
485	Metyrapone (INN)	465	292
486	Minoxidil (INN), its salts and derivatives	597	372
487	Mofebutazone (INN)	134	64
488	Monobenzene (INN)	97, (323)	178
489	Morpholine and its salts	-	344

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
489a	Moskene	544a	421
490	Musk ambrette	133	414
490a	Musk tibetene	137a	422
491	Mustine and its salts	107,161	87
492	Mustine N-oxide and its salts	108	86
492a	<i>Myroxylon pereirae</i>	548a	1136
493	Nalorphine (INN), its salts and ethers	21	20
494	Naphazoline (INN) and its salts	500	244
495	2-Naphthol	496	241
496	β -Naphthol	495	241
497	1- and 2-Naphthylamines and their salts	49%	242
498	α and β -Naphthylamines and their salts	497	242
499	3-(1-Naphthyl)-4-hydroxycoumarin	-	243
500	2-(1-Naphthylmethyl)-2-imidazoline and its salts	494	244
501	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 1981	-	306
502	Narcotine and its salts	520	258
503	Neodymium and its salts		309
504	Neostigmine and its salts	504a	245
505	Nicotine and its salts	-	246
506	Nitrites, inorganic (except sodium nitrite)	-	248
507	Nitrobenzene	-	249
508	Nitrocresols and their alkali metal salts	-	250
509	Nitroderivatives of carbazole	147	72
510	Nitrofurantoin (INN)	511	251
511	N-(5-Nitro-2-furfurylidene)-1-aminohydantoin	510	251

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
512	3-(5-Nitrofurfurylideneamino)oxazolidin-2-one	355	252
513	Nitroglycerine	363, 612	253
514	Nitrosamines		410
515	Nitrostilbenes and their homologues and derivatives	-	256
516	Nitroxoline (INN) and its salts	398	209
517	<i>N,N,N,N',N',N',N',N''</i> -Nonaethyl-2,2',2''-(benzene-1,2,3-triyltrioxy-tris(ethanaminium) triiodide	360	329
518	Noradrenaline and its salts	32, 519	257
519	Norepinephrine (INN) and its salts	32, 518	257
520	Noscapine (INN) and its salts	502	258
521	Nox vomica and its preparations	(659)	305
522	Octamoxin (INN) and its salts	387	202
523	Octamylamine (INN) and its salts		267
524	Octadrine (INN) and its salts	34, 288	28
525	Oestrogens		260
526	Oleandrin		261
527	2-(1,3,4-Oxadiazol-2-yl)phenol	344	208
528	[Oxalylbis(iminoethylene)] bis(<i>o</i> -chlorobenzyl) diethylammonium] salts	24	132
529	Oxanamide (INN) and its derivatives	332	165
530	2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-1 <i>bH</i> -benzo[<i>a</i>]quinolizine and its salts	686	139
531	Oxpheneridine (INN) and its salts	334	172
532	Oxyquinoline and its sulphate, except for the uses provided for in entry number 51 in Part 1 of Annex III	115, 401, 631	395
533	Padimate A (INN)	47	381
534	Paramethasone (INN)	350	186
535	Paraoxon	263	170
536	Parathion (ISO)	264	131

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
537	Parethoxycaine (INN) and its salts	259,411	179
538	Pelletierine and its salts	596	263
539	Pemoline (INN) and its salts	407	212
540	Pentachloroethane	-	264
541	Pentaerythritol chloral	550	266
542	Pentaerithryl tetranitrate	543, 549	265
543	Pentaerithryl tetranitrate (INN)	542, 549	265
544	Pentamethonium bromide (INN)	(545)	120
544a	1,1,3,3,5-Pentamethyl-4,6-dinitroindane	489a	421
545	N,N'-Pentamethylenebis (trimethylammonium)salts	544	120
546	Pentobarbitone and its salts	(70)	220
546a	2-Pentylidenecyclohexanone(CAS No. 25677-40-1) when used as a fragrance ingredient		448
547	Perchloroethylene	690	314
548	Perphenazine (INN) and its salts	(559)	320
548a	Peru Balsam	492a	1136
549	PETN	542, 543	265
550	Petrichloral (INN)	541	266
551	Phenacemide (INN)	562	269
552	Phenaglycodol (INN)	175	95
553	Phenetamine	226	112
554	Phenetunde (INN)	340, 566	272
555	Phenindone (INN)	572	271
556	Phenmetrazine (INN), its derivatives and salts	480	232
557	Phenobarbitone and its salts	(70)	220
558	Phenolphthalein (INN)	114	417
559	Phenothiazine (INN) and its compounds	182, 322, 354, 548,	

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
		609, 611, 708, 738	320
560	Phenprobamate (INN)	574	71
561	Phenprocoumon (INN)	575	273
562	<i>N</i> -Phenylacetylurea	551	269
563	4-Phenylazophenylene-1,3-diamine citrate hydrochloride	191	81
564	Phenylbutazone (INN)	132	67
565	4-Phenylbut-3-en-2-one	95	356
566	(2-Phenylbutyryl)urea	340,554	272
567	<i>N</i> -[2-(<i>a</i> -Phenyl- <i>p</i> -chlorobenzyl)-ethyl]morpholine	265	270
568	1-Phenylcyclopentanecarboxylic acid diethylaminoethylester and its salts	145	169
569	2-Phenylcyclopropylamine (bans-form) and its salts	720	324
570	1-Phenyl-2,3-dimethyl-4-isopropylpyrazol-5-one	618	138
571	<i>o</i> -Phenylenediamine and its salts	242	363
572	2-Phenylindane-1,3-dione	555	271
573	<i>a</i> -Phenyl-2-piperidineacetic acid methyl ester and its salts	476	175
574	3-Phenylpropyl carbamate	560	71
575	3-(<i>a</i> -Phenylpropyl)-4-hydroxycoumarin	561	273
576	1-Phenyl-2-(2-pyridylamino)ethanol	346,580	274
577	2-[1-(2-pyridyl)ethoxy]-ethyl dimethylamine and its salts	311	176
578	2-Phenylquinoline-4-carboxylic acid, its salts and derivatives and salts of those derivatives	193	8
579	6-Phenyl-2,4,7-triaminopteridine and its salts	723	275
580	Phenyramidol	346,576	274
581	Phosphides, metal	-	279
582	Phosphorus	-	279
583	4-Phosphoryloxy-<i>N,N</i>-diethyltryptamine	620	278
584	3-Phthalimidopiperadine-2,6-dione and its salts	702	280

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
585	Phthalylsulphathiazole (INN) and its salts	(676)	307
586	Physostigmav enenosum Balf.	139	281
587	Physostigmine and its salts	319	166
588	<i>Phytolacca Spp</i> and their preparations	-	374
589	Picric acid	743	268
590	Picrotoxin	198	282
591	Pilocarpine and its salts	-	283
592	Pilocarpus aborandi Holmes and its galenical preparations	-	311
593	Pipazetate (INN) and its salts	594	118
594	2-(2-Piperidinoethoxy)ethyl 10-tha-1,9-diazaanthracene-9-carboxylate and its salts	593	118
595	a-Piperidin-2-ylbenzylacetate, laevorotatorythreo-form and its salts	427	284
596	1-(2-Piperidyl)propan-2-one and its salts	538	263
597	6-(Piperidiny)-2,4-pyrimidinediamine-3-oxide , its salts and derivatives	486	372
598	Pipradrol (INN) and its salts	304	285
599	Piprocuarium (INN)	256	137
600	Poldine metisulfate (INN) (Poldine methylsulphate)	86	239
601	Polyacetaldehyde	445	223
602	Potassium cyanide	(388, 390, 409)	111
603	Potassium nitroferricyanide	(15), 604	255
604	Potassium nitroprusside	(15), 603	255
605	Pramocaine (INN)	606	405
606	Pramoxine	605	405
607	Probenecid (INN)	308	161
608	Procainamide (INN) and its salts and derivatives	29	25
609	<i>Prochlorperazine</i> (INN) and its salts	(559)	320

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
610	Progestogens		194
611	Promazine (*) and its salts	(559)	320
612	Promethazine (INN) and its salts	(559)	320
613	Propane-1,2,3-triyl trinitrate	363,513	253
614	Propatylnitrate (INN)	112	206
615	1-Propyl-3-(4-chlorobenzenesulphonyl) urea	183	79
616	2-propyl piperidine	213	290
617	1-(2-Propynyl)cyclohexyl carbamate	383	115
618	Propyphenazone (INN)	570	138
619	<i>Prunus laurocerasus L.</i>	158	291
620	Psilocybine (INN)	583	278
621	Psoralen (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
622	<i>Pyrethrum album L.</i> and its galenical preparations	.	345
623	Pyrianisamine maleate	454	346
624	Pyribenzamine	98,746	347
625	2-(N-2-Pyridyl-N-2-thienylamino)ethyl-dimethylamine and its salts	449	144
626	Pyrithione disulphide + magnesium sulphate	310	396
627	Pyrithione sodium (INN)	-	369
628	Pyrocatechol	80, 154	408
629	Pyrogallol	81	409
630	Quinalbarbitone and its salts	(70)	220
631	Quinolin-8-ol except for the uses provided for in entry number 51 in Part 1 of Annex 11	(401,532)	395
632	Radioactive substances The presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment is permitted, provided that the radioactive substances are not		

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
	enriched for the manufacture of cosmetic products and that their concentration falls within the limits set in the Directive laying down the basic standards for the protection of the health of workers and the general public against dangers arising from ionising radiations (OJ No. 11, 20.2.1959, p. 221/59	-	293
633	Rauwolfia serpentina alkaloids and their salts	634	15
634	Reserpine (INN) and its salts	(633)	15
635	Retinoic acid and its salts	722,759	375
636	Safrole, except for normal content in the natural essences used and provided the concentration does not exceed: a) 100 ppm in the finished product b) 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children	-	360
637	a-Santonin	380	214
637a	<i>Saussurea lappa</i> Clarke	215a	1133
638	<i>Schoenocaulon officinale</i> Lind. (seeds and galenical preparations)	-	332
639	Scopolamine, its salts and derivatives	403	295
640	Secbutobarbitone and its salts	(70)	220
641	Secondary dialkanolamines	111,255,274	411
642	Selenium and its compounds, with the exception of selenium disulphide under the conditions set out in Part 1 of Annex III, entry number 49	-	297
642a	i) Skull, including the brain and eyes, tonsils and spinal cord of bovine animals aged over 12 months, the intestines from the duodenum to the rectum of bovine animals of all ages, and ingredients derived therefrom; ii) Skull, including the brain and spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor tooth erupted through the gum, the spleens of ovine and caprine animals of all ages, and ingredients derived therefrom.		
	However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer: • Transesterification or hydrolysis at at least 200°C at an appropriate corresponding pressure, for 20 minutes (glycerol,		

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
	fatty acids and fatty acid esters) * Saponification with NaOH 12M (glycerol and soap): batch process: at 95°C for 3 hours OR continuous process: at 140°C , 2 bars (2000 hPa) for 8 minutes or equivalent conditions	-	419
643	Sodium cyanide	(388, 390, 409)	111
644	Sodium hexacyclonate (INN)	396	114
645	Sodium nitroferricyanide	(15), 646	255
646	Sodium nitroprusside	(15), 645	255
647	<i>Solanum nigrum L.</i> and its galenical preparations	-	298
648	Spanish Fly	141	69
649	Sparteine (INN) and its salts	433	299
650	Spirolactone (INN)	10	4
651	Squill and its preparations	751	330
652	Stramonium and its preparations	232	301
653	Strontium lactate	-	402
654	Strontium nitrate	-	403
655	Strontium polycarboxylate	-	404
656	Strophantines and their aglucones and their respective derivatives	-	302
657	<i>Strophanthus</i> species and their galenical preparations	-	303
658	Strychnine and its salts	-	304
659	<i>Strychnos</i> species and their galenical preparations	521	305
660	Succinonitrile	-	150
661	Succinylsulphathiazole and its salts	(676)	307
662	Sulfinpyrazone (INN)	303	155
663	Sulphacetamide and its salts	(676)	307
664	Sulphadiazine and its salts	(676)	307
665	Sulphadimethoxine and its salts	(676)	307

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
666	Sulphadimidine and its salts	(676)	307
667	Sulphafurazole and its salts	(676)	307
668	Sulphaguanidine and its salts	(676)	307
669	Sulphamethizole and its salts	(676)	307
670	Sulphamethoxazole and its salts	(676)	307
671	Sulphamethoxydiazine and its salts	(676)	307
672	Sulphamethoxypyridazine and its salts	(676)	307
673	Sulphanilamide and its salts	(676)	307
674	Sulphapyridine and its salts	(676)	307
675	Sulphathiazole and its salts	(676)	307
676	Sulphonamides (Sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the NH ₂ -groups) and their salts	585, 661, 663-675	307
677	Sulthiame	678, 697	308
678	Sultiame (INN)	677, 697	308
679	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical subscription and are referred to in resolution AP (69)2 of the Council of Europe	44	21
680	Tefazoline (*) and its salts .	696	237
681	Tellurium and its compounds	-	312
682	TEPP (ISO)	694	276
683	2-(4-tert-Butyl-2,6-dimethylbenzyl)-2-imidazoline and its salts	765	313
684	4-tert Butylphenol	-	340
685	4-tert Butylpyrocatechol	-	341
686	Tetrabenazine (INN) and its salts	530	139
687	Tetrabromosalicylanilides	-	350
688	Tetracaine (INN) and its salts	280	63

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
689	2,3,7,8-Tetrachlorodibenzo-p-dioxin	-	367
690	Tetrachloroethylene	547	314
691	Tetrachloromethane	149	315
692	Tetrachlorosalicylanilides		348
693	Tetraethylammonium bromide	701	61
694	Tetraethyl pyrophosphate	682	276
695	5,6,6a,7-Tetrahydro-6-methyl-4H-dibenzo[de,g]quinoline-10,11 dihydric alcohol and its salts	59	42
696	2-(5,6,7,8-Tetrahydro-1-naphthylmethyl)-2-imidazoline and its salts	680	237
697	4-(Tetrahydro-2H-1,2-thiazin-2-yl)-benzenesulphonamide S,S-dioxide	677, 678	308
698	Tetrahydrozoline and its salts		394
698a	1,1,4,4-Tetramethyl-6-ethyl-7-acetyl-1,2,3,4-tetrahydro-naphthalene	9,342	362
699	N,2,3,3-Tetramethyl-2-norcamphanamine	438	229
700	Tetramethylthiuram disulphide	711	162
701	Tetrylammonium bromide (INN)	693	61
702	Thalidomide (INN) and its salts	584	280
703	Thallium and its compounds	-	317
704	<i>Thevetia nerifolia</i> Juss. glycoside extract		318
705	Thiamazole (INN)	473, 475	233
706	2,2'-Thiobis(4,6-dichlorophenol)	116	352
707	Thiopentone and its salts	(70)	220
708	Thioridazine (INN) and its salts	(559)	320
709	Thiotepa (INN)	724	310
710	Thiourea and its derivatives (except those listed in Part 1 of Annex II)		327
711	Thiram (ISO)	700	162
712	Thiuram disulphides		354

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
713	Thiuram monosulphides	-	353
714	Thyropropic acid (INN) and its salts	394	9
715	Tolboxane (INN)	718	177
716	Tolbutamide (INN)	135	65
717	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	40	32
718	p-Tolylboric acid ester of 2-methyl-2-propylpropane-1,3-diol	715	177
719	3-o-Tolyloxypropane-1,2-diol	(440)	322
719a	<i>trans</i> -2-Heptenal (CAS No. 18829-55-5) when used as a fragrance ingredient	-	437
719b	<i>trans</i> -2-Hexenal diethyl acetal (CAS No. 67746-30-9) when used as a fragrance ingredient	-	438
719c	<i>trans</i> -2-Hexenal dimethyl acetal (CAS No. 18318-83-7) when used as a fragrance ingredient	-	439
720	Tranylcypromine (INN) and its salts	569	324
721	Tretamine (INN)	725	328
722	Tretinoin (INN) and its salts	635,759	375
723	Triamterene (INN) and its salts	579	275
724	Tri(aziridin-1-yl)phosphine sulphide	709	310
725	2,4,6-Tri(aziridin-1-yl)-1,3-triazine	721	328
726	2,2,2-Tribromoethanol	(727)	326
727	Tribromoethyl alcohol	726	326
728	Tribromsalan (INN)	729	373
729	3,4',5-Tribromosalicylarilide	728	373
730	Trichlormethine (INN) and its salts	747	327
731	Trichloroacetic acid	-	10
732	1,1-Trichloro-2,2-bis(4-chlorophenyl)ethane	196,233	123
733	2,2,2-Trichloroethane-1,1-diol	159	77

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
734	Trichloromethane	169	366
735	N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide	143	370
736	Trichloronitromethane	179	325
737	Tricresyl phosphate	748	277
738	Trifluoperazine (INN) and its salts	(559)	320
739	Trifluoperidol (INN)	349	188
740	3,3',5-Triiodothyroacetic acid and its salts	393	5
741	3,4,5-Trimethoxyphenethylamine and its salts	443	222
742	2,2,6-Trimethyl-4-piperidyl benzoate and its salts	76	51
742a	3,6,10-Trimethyl-3,5,9-undecatrien-2-one (CAS No. 1117-41-5) when used as a fragrance ingredient	-	449
743	2,4,6-Trinitrophenol	589	268
744	Trioxysalen (INN) (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
745	Triparanol (INN)	173	92
746	Tripelennamine (INN)	98,624	347
747	Tris (2-chloroethyl)amine	730	327
748	Tritolyl phosphate	737	277
749	Tuaminoheptane (INN), its isomers and its salts	30	27
750	Thyrothricine (INN)	-	392
751	<i>Urginea</i> scilla Stem and its galenical preparations	651	330
752	Urocanic acid	(406)	418
753	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) (OJ No. L 147, 9.6.1975, p. 13)	-	323
754	Valnoctamide (INN)	339	184

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
755	Veratrine, its salts and galenical preparations	-	331
756	Veratrum spp and their preparations		333
756a	Verbena oil (<i>Lippia citriodora</i> Kunth.) (CAS No. 8024-12-2) when used as a fragrance ingredient		450
757	Vinyl Chloride monomer	-	334
758	Vinylidene chloride	(7, 250)	126
759	Vitamin A acid and its salts	635,722	375
760	Vitamins D2 and D3	140,188,317	335
761	Warfarin (ISO) and its salts	3,399	203
762	Xanthates	16	336
763	Xanthinol	392	135
764	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	41	33
765	Xylometazoline (INN) and its salts	683	313
766	Yohimbine and its salts		337
767	Zirconium and its compounds, with the exception of the complexes under reference no. 50 in Annex 11, Part 1 and of zirconium lakes, salts and pigments of colouring agents listed with reference no. 3 in Annex IV -		391
768	Zoxazolamine (INN)	28	24

In this Annex, names followed by (INN) 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.

ANNEX II - PART 1

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

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2% calculated as sulphur pH up to 12,7 (b) 6% calculated as sulphur pH up to 12,7		(a) Keep out of reach of children Avoid contact with eyes (b) Keep out of reach of children Avoid contact with eyes
	Alpha Hydroxy Acids, - Alpha Mandelic Acid, - Butyric Acid, - Citric Acid, - Glycolic Acid, - Lactic Acid, - Mandelic Acid, - Tartaric Acid and their salts	(a) General use (b) Professional use	(a) Max 10% pH min 3.5 (b) Max 30% pH min 3.0		(a) Sun Alert - Because this product may make your skin more sensitive to the sun, be certain that you apply a broad spectrum sunscreen of at least SPF 15 while using this product, and for a week after you discontinue use. (b) "Sun Alert" statement as above

Reference Number	bs	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
50	Aluminium zirconium chloride hydroxide complexes $Al_2Zr(OH)_2Cl_4$ and the aluminium zirconium chloride hydroxide glycine complexes	Antiperspirants	20% as anhydrous aluminium zirconium chloride hydroxide 5.4% as zirconium	<ol style="list-style-type: none"> The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0.9 and 2.13 Prohibited in aerosol dispensers (sprays) 	Do not apply to irritated or damaged skin.
4	Ammonia		6% calculated as NH_3		Above 2%: Contains ammonia
94	Benzoyl peroxide	Artificial nail systems	0,7% (after mixing)		For professional use only Avoid skin contact Read directions for use
	Beta hydroxy acids -Salicylic acid	General use	Max 2% pH min 3.5		Sun Alert - Because this product may make your skin more sensitive to the sun, be certain that you apply a broad spectrum sunscreen of at least SPF 15 while using this product, and for a week after you discontinue use.

Referent Number	Substance Column 2	Restrictions			Conditions of use and warnings to be printed on the label Column 6
		Field of application and/or use Column 3	Maximum authorised concentration in the finished product Column 4	Other limitations and requirements Column 5	
1a	Boric acid, borates and tetraborates	(a) Talcs (b) Products for oral hygiene (c) Other products (excluding bath products and hair waving products)	(a) 5% (by mass/mass as boric acid) (b) 0.1% (by mass/mass as boric acid) (c) 3% (by mass/mass as boric acid)	(a) Not to be used in products for children under three years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borate exceeds 1.5% (by mass/mass as boric acid) (b) 1. Not to be used in products for children under three years of age (c) 1. Not to be used in products for children under three years of age 2. Not to be used on peeling or irritated skin	(a) 1. Not to be used in products for children under three years of age 2. Not to be used on peeling or irritated skin (b) 1. Not to be swallowed 2. Not to be used in products for children under three years of age (c) 1. Not to be used in products for children under three years of age 2. Not to be used on peeling or irritated skin

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
1b	Tetraborates	(a) Bath Products (b) Hair waving products	(a) 18% (by mass/mass as boric acid) (b) 8% (by mass/mass as boric acid)	(a) Not to be used in products for children under three years of age (b) Rinse well	(a) Not to be used for bathing children under three years of age (b) Rinse well
65	Benzalkonium chloride, bromide and saccharinate	(a) Rinse-off hair (head) care products (b) Other products	(a) 3% (as benzalkonium chloride) (b) 0.1% (as benzalkonium chloride)	(a) In the final product the concentration of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C14 or less must not exceed 0.1% (as benzalkonium chloride)	(a) Avoid contact with the eyes (b) Avoid contact with the eyes
45	Benzyl alcohol	Solvents, perfumes and flavourings			
44	1,3-Bis(hydroxymethyl)imidazoline-2-thione	(a) Hair care preparations (b) Nail care preparations	(a) Up to 2% (b) Up to 2%	(a) Prohibited in aerosol dispensers (sprays) (b) The pH of the product as applied must be less than 4	Contains 1,3-Bis(hydroxymethyl)imidazoline-2-thione

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) pH adjuster - for depilatories (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7% by weight calcium hydroxide	(b) pH value not to exceed pH 12.7 (c) pH value not to exceed pH 11	(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of the reach of children. (b) Contains alkali. Avoid contact with eyes. Keep out of the reach of children.
6	Chlorates of alkali metals	(a) Other uses (b) Toothpaste	(a) 3% (b) 5%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
93	2,4-Diamino-pyrimidine-3-oxide (CAS No. 90028-67-4)	Hair care formulations	1,5%		
10	Diaminophenols (These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1)	Oxidising colouring agents for hair dyeing (a) General use (b) Professional use	10% calculated as free base		(a) Can cause an allergic reaction Contains phenylenediamines Do not use to dye eyelashes or eyebrows (b) For professional use only Contains phenylenediamines Can cause an allergic reaction Wear suitable gloves
7	Dichloromethane		35% (when mixed with 1,1,1-trichloroethane total concentration not to exceed	0,2% as maximum impurity content	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
11	Dichlorophen		35%)		Contains dichlorophen
53	Etidronic acid and its salts (1-Hydroxy-ethylidene-diphosphonic acid and its salts)	(a) Hair care (b) Soap	(a) 1.5% expressed as etidronic acid (b) 0.2% expressed as etidronic acid		
60	Fatty acid dialkylamides and dialkanolamides		Maximum secondary amine content: 0.5%	- Do not use with nitrosating systems - Maximum secondary amine content: 5% (applies to raw materials) - Maximum nitrosamine content: 50µg/kg - Keep in nitrite-free containers	
13	Formaldehyde	Nail hardeners	5% calculated as formaldehyde		Protect cuticles with grease or oil Contains formaldehyde (Only if the concentration exceeds 0.05%)

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair care preparations (b) Skin care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% H ₂ O ₂ (40 volume) present or released (b) 4% H ₂ O ₂ present or released (c) 2% H ₂ O ₂ present or released (d) 0.1% H ₂ O ₂ present or released		(a) Wear suitable gloves (a), (b), (c) Contains hydrogen peroxide Avoid contact with eyes Rinse eyes immediately if product comes into contact with them
15b	Lithium hydroxide	(a) Hair straightener 1. General use 2. Professional use (b) pH adjuster - for	(a) 1. 2% by weight 2. 4.5% by weight	(a) 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 4. (b) pH value not to exceed	(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of the reach of children. 2. For professional use only Avoid contact with eyes. Can cause blindness. (b) Contains alkali.

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		deplatories		pH 12.7	Keep out of the reach of children. Avoid contact with eyes.
		(c) Other uses - as pH adjuster (for rinse-off products only)		(c) pH value not to exceed pH 11	
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as a % of ethanol and isopropyl alcohol		
00	6-Methylcoumarin	Oral hygiene products	0.003%		
9	Methylphenylethylenediamines, their N-substituted derivatives and their salts, with the exception of substance no. 364 in Annex II - EU Directive reference number (These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of	Oxidising colouring agents for hair dyeing (a) General use (b) Professional use only	10% calculated as free base		(a) Can cause an allergic reaction Contains phenylethylenediamines Do not use to dye eyelashes or eyebrows (b) For professional use only Contains phenylethylenediamines Can cause an allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	them does not exceed 1)				Wear suitable gloves
6	Monoalkanolamines, monoalkanolamines and their salts		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none"> - Do not use with nitrosating systems - Minimum purity: 99% - Maximum secondary amine content: 0.5% (applies to raw materials) - Maximum N-nitrosodialkanolamine content: 50µg/kg - Keep in nitrite-free containers 	

Chemical name	Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use or warnings to be indicated on the label
97 Musk ketone (CAS No. 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1.4% in fine fragrance (b) 0.56% in eau de toilette (c) 0.042% in other products		
96 Musk xylene (CAS No. 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1.0% in fine fragrance (b) 0.4% in eau de toilette (c) 0.03% in other products		
16 1-Naphthol (CAS No. 90-15-3) and its salts	Oxidising colouring agents for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
18	Nitromethane	Rust inhibitor	0.3%		
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		For professional use only
19	Phenol and its alkali salts	Soap and shampoos	% calculated as phenol		Contains phenol
54	1-Phenoxypropan-2-ol	Rinse-off products only Prohibited in oral hygiene products	%	As preservative, see Annex VI Part 1, No. 43 - EU Directive reference number	
8	m- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of	Oxidising colouring agents for hair dyeing (a) General use	6% calculated as free base		(a) Can cause an allergic reaction Contains phenylenediamines Do not use to dye eyelashes

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	o-Phenylenediamines, with the exception of those derivatives listed elsewhere in this Annex (These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1)	(b) Professional use			(b) For professional use only Contains phenylenediamines Can cause an allergic reaction Wear suitable gloves
∞	Polyacrylamides	(a) Body care leave-on products (b) Other cosmetic products		(a) Maximum residual Acrylamide content 0.1 mg/kg (b) Maximum residual Acrylamide content 0.5 mg/kg	
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent (b) Hair straightener 1. General use	(a) 5% by weight (b) 1. 2% by weight	(a) (b) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide In cases of mixtures, the sum total should not exceed the limits given in column 4	(a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children (b) 1. Contains alkali Avoid contact with eyes Can cause blindness

Reference Number	Substance	Restrictions				Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	Column 6	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	
		2. Professional use (c) pH adjuster - depilatories (d) Other uses as pH adjuster	2. 4.5% by weight (c) Up to pH 12.7 (d) Up to pH 11		Keep out of reach of children 2. Professional use only Avoid contact with eyes Can cause blindness (c) Avoid contact with eyes Keep out of reach of children	
21	Quinine and its salts	(a) Shampoo (b) Hair lotions	(a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base			
51	Quinolin-8-ol and bis(8-hydroxyquinolinium)sulphate	(a) Stabiliser for hydrogen peroxide in rinse-off hair care preparations (b) Stabiliser for hydrogen peroxide in non rinse-off hair care preparations	(a) 0.3% calculated as base (b) 0.03% calculated as base			

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
49	Selenium disulphide	Anti-dandruff shampoo	1%		Contains selenium disulphide Avoid contact with eyes or damaged skin
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		Contains silver nitrate Rinse eyes immediately if product comes into contact with them
17	Sodium nitrite	Rust inhibitor	0.2%		
63	Strontium hydroxide	pH regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		Do not use with secondary and/or tertiary amines or other substances forming nitrosamines Keep out of the reach of children Avoid contact with eyes
64	Strontium peroxide	Rinse-off hair care preparations for professional use	4.5% calculated as strontium in the ready-for-use preparations		Avoid contact with eyes Rinse eyes immediately if product comes into contact with them For professional use only Wear suitable gloves

Referent Number	est			Conditions of use and warnings to be printed on the label Column 6
	Field of application and/or use Column 3	Maximum authorised concentration in the finished product Column 4	Other limitations and requirements Column 5	
59	Talc: Hydrated magnesium silicate	Powdery products intended to be used for children under three years of age Other products		Keep powder away from children's nose and mouth
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products - General use - Professional use (b) Depilatories (c) Other hair care products which are removed after application	- 8% ready for use pH 7.0 - 9.5 - 11% ready for use pH 7.0 - 9.5 - 5% ready for use pH 7.0 - 12.7 - 2% ready for use pH 7.0 - 9.5 Percentages calculated as thioglycolic acid	(B) Contains thioglycolate Follow the instructions Keep out of reach of children For professional use only (b) and (c) Contains thioglycolate Follow the Instructions Keep out of reach of children

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
2b	Thioglycolic acid esters	Hair waving or straightening products - General use - Professional use	- 8% ready for use pH 6.0 - 9.5 - 11% ready for use pH 6.0 - 9.5 Percentages calculated as thioglycolic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: - May cause sensitisation in the event of skin contact - Avoid contact with eyes - In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice - Wear suitable gloves	- Contains thioglycolate - Follow the instructions - Keep out of reach of children - For professional use only
5	Tosylchloramide sodium		0.2%		
00	Trialkylamines, trialkanoamines and their salts	(a) Non rinse-off products (b) Other products	(a) 2.5%	(a) (b) - Do not use with nitrosating systems - Minimum purity 99% - Maximum secondary amine content: 0.5%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
				(concerns raw materials) - Maximum N-nitrosodihydroxybenzylamine content: 50 µg/kg - Keep in nitrite-free containers	
24	Water-soluble zinc salts with the exception of zinc-4-hydroxy-benzenesulphonate and zinc pyrrithione		1% calculated as zinc		
25	Zinc-4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		Avoid contact with eyes

ANNEX II - PART 2
LIST OF SUBSTANCES THAT COSMETIC ORAL HYGIENE PRODUCTS MUST NOT CONTAIN, EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
34	Aluminium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains aluminium fluoride
33	Ammonium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains ammonium fluoride

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
42	Ammonium fluorosilicate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains ammonium fluorosilicate
26	Ammonium monofluorophosphate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains ammonium monofluorophosphate
30	Calcium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains calcium fluoride

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Calcium glycerophosphate	Oral hygiene products	0.06% - 0.2% m/m		Contains calcium glycerophosphate
29	Calcium monofluorophosphate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains calcium monofluorophosphate
6	Chlorates of alkali metals	Toothpaste	Max 5% m/m		
	Disodium pyrophosphate	Oral hygiene products	Max 3.3% as soluble pyrophosphate		Contains disodium pyrophosphate
36	Hexadecyl ammonium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains hexadecyl ammonium fluoride

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
37	3-(N-hexadecyl-N-2-hydroxyethyl ammonio)propylbis (2-hydroxyethyl)ammonium dihydrofluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains 3-(N-hexadecyl-N-2-hydroxyethyl ammonio)propylbis (2-hydroxyethyl) ammonium dihydrofluoride
12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (Refer Annex III Part 1)	Oral hygiene products	0.1% of H ₂ O ₂ present or released		Contains hydrogen peroxide
15	Triclosan (INN)	Oral hygiene products	0.2% - 0.35% m/m		Contains triclosan
56	Magnesium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains magnesium fluoride

Reference Number	Substance	Restrictions			Other limitations and requirements	printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	
43	Magnesium fluorosilicate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains magnesium fluorosilicate	
46	6-Methylcoumarin	Oral hygiene products	0.003%			
47	Nicomethanol hydrofluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains nicomethanol hydrofluoride	
39	Octadecenyl-ammonium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to		Contains octadecenyl-ammonium fluoride	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
32	Potassium fluoride	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains potassium fluoride
41	Potassium fluorosilicate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains potassium fluorosilicate
28	tas	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion		Contains potassium monofluorophosphate

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
			concentration not to exceed 0.15% m/m.		
31	Sodium fluoride	Oral hygiene products			Contains sodium fluoride
40	Sodium fluorosilicate	Oral hygiene products			Contains sodium fluorosilicate
27	Sodium monofluorophosphate	Oral hygiene products	0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex,		Contains sodium monofluorophosphate

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
35	Stannous fluoride	Oral hygiene products	total fluoride ion concentration not to exceed 0.15% m/m. 0.075% - 0.15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains stannous fluoride
58	Strontium acetate hemihydrate	Toothpaste	3.5% calculated as strontium When mixed with other permitted strontium products the total strontium content not to exceed 3.5%		Contains strontium acetate Frequent use by children is not advisable
57	Strontium chloride hexahydrate	Toothpaste	3.5% calculated as strontium When mixed with other permitted strontium products the total		Contains strontium chloride Frequent use by children is not advisable

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Strontium salts	Oral hygiene products	strontium content not to exceed 3,5% 3,0% - 5,0% m/m as strontium		Contains strontium salts
	Tetra potassium pyrophosphate	Oral hygiene products	Max 3,3% as soluble pyrophosphate		Contains tetrapotassium pyrophosphate
	Tetra sodium pyrophosphate	Oral hygiene products	Max 3,3% as soluble pyrophosphate		Contains tetrasodium pyrophosphate
38	N N' N"-tris(polyoxyethylene)-N-hexa-decylpropylenediamine dihydrofluoride	Oral hygiene products	0,075% - 0,15% m/m calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0,15% m/m.		Contains N N' N"-tris (polyoxyethylene)-N-hexa-decylpropylene diarnedihydrofluoride
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzene-sulphonate and zinc	Oral hygiene products	Max 1% m/m calculated as zinc		Contains water-soluble zinc salts with the exception of zinc 4-hydroxy-benzene-

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	pyrithione				Column 6 sulphonate and zinc pyrithione

ANNEX II - 000 3

**LIST OF SUBSTANCES THAT COSMETIC HAIR DYES MUST NOT CONTAIN,
EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN**

Note 1: Refer to Reference Numbers 8, 9, 10, 16 and 22 in Annex II Part 1 for hair dyes not listed in Part 3

Reference Number	Substance	Field of application and/or use	Restrictions		Other limitations and requirements	Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Column 4		
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 6
45	Acid Black 52 (CAS No. 16279-54-2) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%		

Reference Number	Substance Column 2	Restrictions			Conditions of use and warnings to be printed on the label Column 6
		Field of application and/or use Column 3	Maximum authorised concentration in the finished product Column 4	Other limitations and requirements Column 5	
58	Acid Red 33 (CAS No. 3557-66-6) (C117200) and its salts	Non-oxidising colouring agent for hair dyeing	2.0%		
56	2-Amino-6-chloro-4-nitrophenol (CAS No. 6358-09-4) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
		(b) Non-oxidising colouring agent for hair dyeing	(b) 2.0%		
41	6-Amino-o-cresol (CAS No. 17672-22-9) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
19	3-Amino-2,4-dichlorophenol (CAS No. 61693-43-4) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon	Can cause an allergic reaction

Reference Number	Substance Column 2	Restrictions			Conditions of use and warnings to be printed on the label Column 6
		Field of application and/or use Column 3	Maximum authorised concentration in the finished product Column 4	Other limitations and requirements Column 5	
35	4-Amino-2-hydroxytoluene (CAS No. 2835-95-2) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
2	2-Amino-3-nitrophenol (CAS No. 603-85-0) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	(a) (b) Can cause an allergic reaction
		(b) Non-oxidising colouring agent for hair dyeing	(b) 3.0%		
3	4-Amino-3-nitrophenol (CAS No. 610-81-1) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	(a) (b) Can cause an allergic reaction
		(b) Non-oxidising colouring agent for hair dyeing	(b) 3.0%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
39	2-Amino-4-hydroxyethyl aminoanisole (CAS No. 83763-47-7) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
38	4-Amino-m-cresol (CAS No. 2835-99-6) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
42	2-Aminomethyl-p-aminophenol (CAS No. 79362-72-0) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
5	m-Aminophenol (CAS No. 691-27-5) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction

Reference Number	Substance Column 2	Restrictions		Conditions of use and warnings to be printed on the label Column 6
		Field of application and/or use Column 3	Maximum authorised concentration in the finished product Column 4	
60	Basic Violet 14 (CAS No. 632-99-5) (CI 42510) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 0.3%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15%
		(b) Non-oxidising colouring agent for hair dyeing	(b) 0.3%	
18	1,3-Bis-(2,4-diamino-phenoxy) propane (CAS No. 81992-72-0)	Oxidising colouring agent for hair dyeing		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%
55	2-Chloro-6-ethylamino-4-nitrophenol (CAS No. 131657-78-8) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%
		(b) Non-oxidising colouring	(b) 3.0%	

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Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		agent for hair dyeing			
30	2-Chloro-5-nitro-N-hydroxy ethyl-p-phenylenediamine (CAS No. 50610-28-1) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
		(b) Non-oxidising colouring agent for hair dyeing	(b) 1.0%		
13	2,4-Diamino-5-methylphenoxy ethanol (CAS No. 141614-05-3) and its salts	Oxidising colouring agent for hair dyeing	3.0%		Can cause an allergic reaction
				In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
17	2,4-Diamino-5-methylphenetol (CAS No. 141614-04-2) and its salts	Oxidising colouring agent for hair dyeing	2.0%		Can cause an allergic reaction
				In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
40	3,4-Diaminobenzoic acid (CAS No. 619-05-6) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
36	2,4-Diaminophenoxyethanol (CAS No. 709-43-19-5) and its salts	Oxidising colouring agent for hair dyeing	4.0%		
6	2,6-Dihydroxy-3,4-dimethyl pyridine (CAS No. 845-40-47-5) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 2.0%	Can cause an allergic reaction
25	2,6-Dimethoxy-3,5-pyridine diamine (CAS No. 85679-78-3) and its salts	Oxidising colouring agent for hair dyeing	0.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
54	HC Blue No.9 (CAS No. 114037-42-1) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%		
				In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
9	HC Blue No. 11 (CAS No. 23020-15-2) and its salts	(b) Non-oxidising colouring agent for hair dyeing	(b) 1.0%		
		(a) Oxidising colouring agent for hair dyeing	(a) 3.0%		
				In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	(a) (b) Can cause an allergic reaction
16	HC Blue No. 12 (CAS No. 104516-93-0) and its salts	(b) Non-oxidising colouring agent for hair dyeing	(b) 2.0%		
		(a) Oxidising colouring agent for hair dyeing	(a) 1.5%		
				In combination with hydrogen peroxide the	(a) (b) Can cause an allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		(b) Non-oxidising colouring agent for hair dyeing	(b) 1.5%	Maximum use concentration upon application is 0.75%	
47	HC Blue No. 2 (CAS No. 33229-34-4) and its salts	Non-oxidising colouring agent for hair dyeing	2.6%		
53	HC Blue No. 10 (CAS No. 173994-75-7) and its salts	Oxidising colouring agent for hair dyeing	2.0%		
26	HC Orange No. 2 (CAS No. 85765-48-6) and its salts	Non-oxidising colouring agent for hair dyeing	1.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
50	HC Red No. 10 (CAS No. 95576-89-9) and its salts AND	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%		In combination with hydrogen peroxide the maximum use

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
				Maximum use	
				concentration upon application is 0.25%	
		(b) Non-oxidising colouring agent for hair dyeing	(b) 0.5%		
24	HC Yellow No. 10 (CAS No. 109023-83-8) and its salts	Non-oxidising colouring agent for hair dyeing	0.2%		
52	HC Yellow No. 12 (CAS No. 59320-13-7) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 1.0%		
				In combination with hydrogen peroxide the maximum use concentration upon application is 0.5%	
		(b) Non-oxidising colouring agent for hair dyeing	(b) 0.5%		
51	HC Yellow No. 6 (CAS No. 104333-00-8) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%		
				In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
22	Hydroxybenzomorpholine (CAS No. 26021-57-6) and its salts	(b) Non-oxidising colouring agent for hair dyeing	(b) 1.0%		
		Oxidising colouring agent for hair dyeing	2.0%		
44	Hydroxyethyl-3,4-methylene dioxyaniline (CAS No. 81328-90-0) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction
43	Hydroxyethylaminomethyl-p-aminophenol (CAS No. 110962-48-0) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
15	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No. 12252-11-3) and its salts	Non-oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	Can cause an allergic reaction

Reference Number	Substance	Field of application and/or use		Restrictions		Other limitations and requirements	Conditions of use and warnings to be printed on the label
		Column 3	Column 4	Column 5	Column 6		
10	Hydroxyethyl-2-nitro-p-toluidine (CAS No. 100418-33-5) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	(a) (b) Can cause an allergic reaction		
		(b) Non-oxidising colouring agent for hair dyeing	(b) 1.0%				
29	2-Hydroxy-ethylamino-5-nitro anisole (CAS No. 66005-81-6) and its salts	Non-oxidising colouring agent for hair dyeing	1.0%				
11	2-Hydroxy-ethylpicramic acid (CAS No. 99610-72-7) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 3.0%		(a) (b) Can cause an allergic reaction		
		(b) Non-oxidising colouring agent for hair dyeing	(b) 2.0%				
7	4-Hydroxypropylamino-3-nitrophenol (CAS No. 92952-81-3)	(a) Oxidising colouring agent for hair dyeing	(a) 5.2%		(a) (b) Can cause an allergic reaction		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	and its salts			maximum use concentration upon application is 2.6%	
33	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) (CAS No. 128728-30-6) and its salts	(b) Non-oxidising colouring agent for hair dyeing	(b) 2.6%		
		Oxidising colouring agent for hair dyeing	3.0%		
21	2-Methyl-5-hydroxyethyl aminophenol (CAS No. 55302-98-0) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	Can cause an allergic reaction
28	3-Methylamino-4-nitrophenoxy ethanol (CAS No. 59820-63-2) and its salts	Non-oxidising colouring agent for hair dyeing	1.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction
12	p-Methylaminophenol (CAS No. 150-75-4) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	Can cause an allergic reaction

Reference Number	Substance Column 2	Field of application and/or use Column 3		Restrictions Maximum authorised concentration in the finished product Column 4		Other limitations and requirements Column 5	Conditions of use and warnings to be printed on the label Column 6
4	2,7-Naphthalenediol (CAS No. 562-17-2) and its salts	Oxidising colouring agent for hair dyeing		1.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 0.5%	
48	3-Nitro-p-hydroxyethylamino phenol (CAS No. 66235-31-6) and its salts	(a) Oxidising colouring agent for hair dyeing		(a) 6.0%			
		(b) Non-oxidising colouring agent for hair dyeing		(b) 6.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 3.0%	
46	2-Nitro-p-phenylenediamine (CAS No. 5307-14-2) and its salts	(a) Oxidising colouring agent for hair dyeing		(a) 0.3%			
						In combination with hydrogen peroxide the maximum use concentration upon application is 0.15%	

ANNEX III

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS

Field of application:

- Column 3 : Colouring agents allowed in all cosmetic products.
- Column 4 : Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes and in eye make-up and eye make-up remover.
- Column 5 : Colouring agents allowed exclusively in cosmetic products not intended to come into contact with the mucous membranes.
- Column 6 : Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
		3	4	5	6	
Column 1	Column 2	3	4	5	6	Column 7
10006	Green				X	
10020	Green			X		
10316 (2)	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		

- (1) Lakes or salts of these colouring agents using substances not prohibited under Annex I or not excluded under Annex IV from the scope of these regulations shall also be allowed.
- (2) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
		3	4	5	6	
column 1	Column 2	Column 7				
12085 (2)	Red	X				3% maximum concentration in the finished product
12120	Red				X	
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				
14270	Orange	X				
14700	Red	X				
14720	Red	X				
14815	Red	X				
15510 (2)	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 6	Red	X				3% maximum concentration in the finished product
15800	Red			X		
15850 (2)	Red	X				
15865 (2)	Red	X				
15880	Red	X				
15980	Orange	X				
15985 (2)	Yellow	X				
16035	Red	X				
16185	Red	X				
16230	Orange			X		

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
		3	4	5	6	
Column I	Column 2					Column 7
16255 (2)	Red	X				
16290	Red	X				
17200 (2)		X				
				X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 (2)	Yellow	X				
20040	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20470	Black				X	
21100	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21230	Yellow			X		
24790	Red					
26100	Red			X		Purity criteria: aniline $\leq 0.2\%$ 2-naphthol $\leq 0.2\%$ 4-aminoazobenzene $\leq 0.1\%$ 1-(phenylazo)-2 naphthol $\leq 3\%$ 1-[2-(phenylazo)phenylazo]-2-Naphtalenol $\leq 2\%$
27755	Black	X				
28440	Black	X				
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				
40825	Orange	X				
40850	Orange	X				
42045	Blue			X		

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
42051 (2)	Blue	X				
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	5 ppm maximum concentration in finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				
45100	Red				X	
45190	V i				X	
45220	Red				X	
45350	Yellow	X				6% maximum concentration in the finished product
45370 (2)	Orange	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45380 (2)	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
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1%
45405	Red		X			Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45410 (2)	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
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

47005	Yellow	X			
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			
69825	Blue	X			
71105	Orange			X	
73000	Blue	X			
73015	Blue	X			
73360	Red	X			
73385	Violet	X			
73900	Violet				X
73915	Red				X
74100	Blue				X
74160	Blue	X			
74180	Blue				X

Colour index number or denomination	Colour	Field of application				Other conditions and requirements
		3	4	5	6	
Column 1	Column 2					Column 7
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				
75125	Yellow	X				
75130	Orange	X				
75135	Yellow	X				
75170	White	X				
75300	Yellow	X				
75470	Red	X				
75810	Green	X				
77000	White	X				
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				
77231	White	X				
77266	Black	X				
	Black	X				
77266 : 1	Black	X				
77288	Green	X				Free from chromate ions
77289	Green	X				Free from chromate ions
77346	Green	X				
77400	Brown	X				
77480	Brown	X				
77489	Orange	X				
77491	Red	X				

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
		3	4	5	6	
Column 1	Column 2					Column 7
77492	Yellow	X				
77499	Black	X				
77510	Blue	X				Free from cyanide ions
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				
77891	White	X				
77947	White	X				
Lactoflavin	Yellow	X				
Caramel	Brown	X				
Capsanthin, capsorubin	Orange	X				
Beetroot red	Red	X				
Anthocyanins	Red	X				
Aluminium, zinc, magnesium and calcium stearates	White	X				
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	
Acid red 195	Red			X		

ANNEX IV

LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THESE REGULATIONS

Strontium and its compounds (with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex I), strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in Annex II, Part 1, and of strontium lakes, pigments and salts of the colouring agents listed with the reference (2) in Annex III.

ANNEX V

LIST OF PRESERVATIVES THAT COSMETICS PRODUCTS MAY CONTAIN

1. **Preservatives** are substances which may be added to cosmetic products for the primary purpose of **inhibiting** the development of micro-organisms in such **products**.
 2. The substances marked with the (+) symbol may also be added to cosmetic products in Concentrations other than those **laid** down in this Annex for other specific purposes apparent from the presentation of the products, for example: as deodorants in soaps or as **anti-dandruff** agents in shampoos.
 3. Other substances **used** in the formulation of cosmetic products may also have anti-microbial properties and thus help in the preservation of the products, as, for **instance**, many essential oils and some alcohols. These substances are not included in this Annex
 4. For the purposes **of** this **list** -

'**Salts**' is taken to mean: salts **of** the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.

'**Esters**' is taken to mean: esters **of** methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.
 5. All finished products containing formaldehyde or substances in this Annex which release formaldehyde must be labelled with the warning: "contains formaldehyde" **where** the concentration of formaldehyde in the finished product exceeds 0,05%.
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ANNEX V

List of preservatives which Cosmetic Products may contain

Colipa number	Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 72	44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (+)	0,1%		
P 2	1	Benzoic acid, its salts and esters (+) (Refer Annex VII, Part 1)	0,5% (acid)		
P 71	16	Benzalkonium chloride, bromide and saccharinate (Alkyl (C8-C18) dimethyl benzyl ammonium chloride, bromide and saccharinate) (+)	0,1% calculated as benzalkonium chloride		Avoid contact with the eyes
P 70	53	Benzethonium chloride	0,1%	(a) Rinse-off products, (b) Leave-on products other than for oral care use	
P 67	34	Benzyl alcohol (+)	1%		
P 21	55	Benzylformal	0,15%	Only for products to be removed by rinsing	
P 25	37	Bromochlorophen 6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (+)	0,1%		
P 65	33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (+)	0,6%		

Colipa Number	Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 23	20	5-Bromo-5-nitro-1,3 dioxane	0,1%	Only for products which are rinsed off after use Avoid formation of nitrosamines	
P 24	21	Bronopol (INN) (+)	0,1%	Avoid formation of nitrosamines	
P 35	42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3% expressed as chlorhexidine		
P 27	41	2-Chloroacetamide	0,3%		Contains chloroacetamide
P 68	11	Chlorobutanol (INN)	0,5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
P 30	24	4-Chloro-m-cresol (+)	0,2%	Prohibited in products intended to come into contact with mucous membranes	
P 56	39	Mixture of 5-Chloro-2-methylisothiazol-3 (2H)-one and 2-methylisothiazol-3 (2H)-one with magnesium chloride and magnesium nitrate	0,0015% (of mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3 (2H)-one and 2-methylisothiazol-3 (2H)-one)		
P 22	40	Chlorophene 2-Benzyl-4-chlorophenol	0,2%		

Colipa Number	Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 4	50	Chlorphenesin	0,3%		
P 64	32	3-(p-Chlorophenoxy)-propane-1,2 diol			
P 37	26	1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-dimethyl-butan-2-one (+)	0,5%		
P 5	13	4-Chloro-3,5-xyleneol (+) Dehydroacetic acid	0,5%		
P 77	36	(3-Acetyl-6-methylpyran-2,4 (3H)-dione) and its salts	0,6% (acid)	Prohibited in aerosol dispensers (sprays)	
P 9	15	1,2-Dibromo-2,4-dicyanobutane Dibromohexamidine 3,3'-Dibromo-4,4'-hexamethylene-dicyclobenzamidine and its salts (including isothionate)	0,1%	Rinse-off products only	
P 74	22	2,4-Dichlorobenzyl alcohol (+)	0,15%		
P 75	45	4,4-Dimethyl-1,3-oxazolidine	0,1%		
				The pH of the finished product not to be lower than 6	

Colipa Number	Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 90	49	5-Ethyl-3,7-dioxo-1-azabicyclo [3,3,0] octane	0,3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
P 6	14	Formic acid and its sodium salt (+)	0,5% (expressed as acid)		
P 9	5	Formaldehyde and paraformaldehyde (+)	0,2% (except for products for oral hygiene) 0,1% (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
P 44	38	4-isopropyl-m-cresol	0,1%		
P 76	48	Glutaraldehyde (Pentane-1,5-dial)	0,1%	Prohibited in aerosol dispensers (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0,05%)
P 8	47	Hexamidine 1,6-Di(4-aminidinophenoxy)-N-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (+)	0,1%		
P 20	19	Hexetidine (INN) (+)	0,1%		

Colipa Number	Reference number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 82	12	4-Hydroxybenzoic acid and its salts and esters (+)	0,4% (acid) for 1 ester, 0,8% (acid) for mixtures of esters		
P 79	46	N-(1-hydroxymethyl)-N-(dihydroxymethyl)-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0,5%		
P 59	35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl) 2-pyridon and its monethanolamine salt (+)	(a) 1% (b) 0,5%	(a) For products which are rinsed off after use (b) For other products	
P 43	27	Imidazolidinyl urea 3,3-Bis (1-hydroxymethyl-2,5 dioxoimidazolidin-4-yl)-1,1'-methyleneurea (+)	0,6%		
P 91	56	3-Iodo-2-propylbutylcarbamate	0,05%	1. Not to be used for oral hygiene and lip care products 2. If the concentration in products intended to remain on the skin exceeds 0,02% acid the phrase 'contains iodine'	Contains iodine
P 44	38	4-Isopropyl-m-cresol	0,1%		
P 55	30	Methanamine Hexamethylenetetramine (INN) (+)	0,15%		

Colipa Number	Reference number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 63	31	Methanamine 3-chloroethylochloride (INN)	0,2%		
P 53	57	Methylisothiazoline (INCI)	0,01%		
P 54	29	2-Phenoxyethanol (+)	1%		
P 48	43	1-Phenoxypropan-2-ol	1,0%	- Only for rinse-off products	
P 47	17	Phenylmercuric salts (including borate)	0,007% (of Hg) If mixed with other mercurial compounds authorised by these regulations, the maximum concentration of Hg to remain fixed at 0,007%	For eye make-up and eye make-up remover only	Contains phenylmercuric compounds
P 52	7	o-Phenylphenol (Biphenyl-2-ol) and its salts (+)	0,2% expressed as phenol		
P 13	28	Poly-1-hexamethyleneguanide hydrochloride (+)	0,3%		
P 14	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 3 years of age, except for shampoos.	Not to be used for children under 3 years of age (Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.)

Colipa Number	Reference number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 93	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.	
P 84	51	Sodium hydroxymethylamino acetate Sodium hydroxymethylglycinate	0,5%		
P 68	10	Sodium iodate	0,1%	Rinse-off products only	
P 15	4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (+)	0,6% (acid)		
P 51	9	Sulphites (inorganic) and hydrogensulphites (+)	0,2% expressed as free SO ₂		
P 12	16	Thiomersal (INN)	0,007% (of Hg) If mixed with other mercurial compounds authorised by these regulations, the maximum concentration of Hg to remain fixed at 0,007%	For eye make-up and eye make-up remover only	Contains thiomersal

Collpa Number	Reference number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
P 29	23	Triclocarban (INN) (+)	0,2%	Purity criteria: 3,3',4,4'-tetra-chloroazobenzene less than 1 ppm 3,3',4,4'-tetra-chloroazoxybenzene less than 1 ppm	
P 32	25	Triclosan (INN) (+)	0,3%		
P 16	18	Undec-10-enoic acid and salts (+)	0,2% (acid)		
P 81	8	Zinc Pyrithione (INN) (+) (See Annex III, Part 1 and 2)	0,5%	Authorised in products which are rinsed off after use. Forbidden in products for oral hygiene	

ANNEX VI

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

For the purpose of these regulations, UV filters are substances which, when contained in cosmetic sunscreen products, are specifically intended to filter certain UV rays in order to protect the skin from the 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.

ANNEX VI
LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

Colipa Number	Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements		
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 6
		Benzophenone-1	10%			
		Benzophenone-2 2,2',4,4'-Tetrahydroxybenzophenone	10%			
S-38	4	Benzophenone-3 Oxybenzone 2-hydroxy-4-methoxybenzophenone	10%			Contains oxybenzone (Not required if concentration is 0.5% or less or when it is used only for product protection purposes)
		Benzophenone-4 Sulisobenzone 2-Hydroxy-4-methoxybenzophenone 5-sulfonic acid	5% (of acid)			
S-40	22	Benzophenone-5 2-Hydroxy-4-methoxybenzophenone 5-sulphonic acid sodium salt	5% (of acid)			

Collipa Number	Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements		
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	
		Benzophenone-6 2,2-Dihydroxydimethoxybenzophenone	10%			
		Benzophenone-8 2,2-Dihydroxy-4,4-dimethoxybenzophenone	3%			
		Benzophenone-9 Disodium-2,2'-dihydroxy-4,4'-dimethoxy-5,5'-disulphobenzophenone				
S61	19	3-Benzylidene Camphor	2%			
S69	9	Benzylidene camphor sulphonic acid Alpha-(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid and its salts	6% (expressed as acid)			
S66	8	Butyl methoxydibenzoylmethane 1-(4-tert-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5%			
S57	2	Camphor benzalkonium methosulphate N,N,N-trimethyl-4-(2-oxoborn-3-ylidene methyl)anilinium methyl sulphate	6%			

Colipa Number	Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements		
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	
		Cinoxate 2-Ethoxyethyl 4-methoxycinnamate	5%			
		DEA-methoxycinnamate 4-Methoxycinnamic acid salts (potassium, sodium, diethanolamine salts)	8%			
S76	17	Benzoic acid, 4,4-((6-((1,1-dimethylethyl) amino carbonyl) phenyl amino)-1,3,5-triazine-2,4-diyldiimino) bis-bis (2-ethylhexyl) ester	10%			
		Digalloyl trioleate 3,4-Dihydroxy-5-(3,4,5-trihydroxy-benzoyloxy) benzoic acid trioleate	5%			
		Diisopropyl methyl cinnamate	10%			
		1-(3,4-Dimethoxyphenyl)-4,4-dimethyl-1,3-pentanedione	7%			
S74	26	Dimethyldiethyl-benzalmonate	10%			
S73	16	Drometrizole trisiloxane Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-	15%			

Colipa Number	Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements	Column 6	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	
		(2-methyl-3-(1,3,3,3-tetraethyl-1-(trimethyl-silyloxy)-disiloxy)propyl)				
		Ethyl dihydroxypropyl PABA Ethyl 4-bis(hydroxypropyl) aminobenzoate, mixed isomers	5%			
		2-Ethylhexyl dimethoxybenzylidene Dioximidazolidene propionate	3%			
S8	21	Ethyl hexyl dimethyl PABA 4-Dimethyl-amino-benzoate of ethyl-2-hexyl	8%			
S28	12	Ethyl hexyl methoxycinnamate 2-Ethylhexyl 4-methoxycinnamate	10%			
S81	25	Bis-ethylhexyloxyphenol methoxyphenyl triazine (1,3,5)-Triazine-2,4-bis(4-(2-ethyl-hexyloxy)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl)	10%			
S13	20	2-Ethylhexyl salicylate Octyl salicylate	5%			
S69	15	Ethyl hexyl triazone	5%			

Collpa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		1,3,5-triazine			
		Ferulic acid	10%		
		Glyceryl ethylhexanoate dimethoxycinnamate	10%		
		Glyceryl PABA Glycerol 1-(4-aminobenzoate) 4-aminobenzoic acid-1-glyceryl ester	5%		
		4-(2- <i>β</i> -glucopyranosiloxy)propoxy-2-hydroxy benzophenone	5%		
		Homosalate	10%		
S27	14	Isomyl p-methoxycinnamate Isopentyl-4-methoxycinnamate (mixed isomers)	10%		
		Isopropylbenzyl salicylate	4%		
		Isopropyl p-methoxycinnamate / Diisopropyl cinnamate esters mixture	10%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
S60	18	Menthyl anthranilate 5-menthyl-2-(methylthio)cyclohexanol-2-aminobenzoate	5%		
S60	18	3-(4-Methylbenzylidene)-d-1-camphor (4-Methylbenzylidene Camphor)	4%		
S79	23	Methylbis(trimethylsiloxy) silylisopentyl trimethoxycinnamate	7.5%		
S80	24	2,2-Methylene-bis-6-(2H-benzotiazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol	10%		
S80	24	Monosodium salt of 2,2-bis-(1,4-phenylene) 1H-benzimidazole-4,6-disulphonic acid	10% (of acid)		
S32	10	Octocrylene 2-Cyano-3,3-diphenyl acrylic acid, 2,3-ethylhexyl ester	10% (expressed as acid)		
S1	1	PABA 4-Aminobenzoic acid	5%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
S3	13	PEG-25 PABA Ethoxylated ethyl-4-amino-benzoate	10%		
S-45	6	Phenylbenzimidazole sulphonlic acid 2-Phenylbenzimidazole-S-sulphonlic acid and its potassium, sodium and triethanolamine salts	8% (expressed as acid)		
S72	11	Polyacrylamidomethyl benzylidene camphor Polymer of N-(2and 4)-[2-oxoborn-3-ylidene methyl(benzyl) acrylamide	6%		
		TEA-salicylate Salicylic acid salts (potassium, sodium and triethanolamine salts)	2% (expressed as acid)		
S71	7	Terephthalylidene dicamphor sulphonlic acid 3,3-(1,4-phenylenedimethylidene)bis [7,7-dimethyl-2-oxabicyclo-(2,2,1)-hept-1-ylmethane sulphonlic acid] and its salts	10% (expressed as acid)		
S75	27	Titanium dioxide Zinc oxide	25%		
			Up to 25%		

Colipa Number Column 1	Reference Number Column 2	Substance Column 3	Restrictions		Conditions of use and warnings to be printed on the label Column 6
			Maximum authorised concentration in the finished product Column 4	Other limitations and requirements Column 5	