
 STATUTORY INSTRUMENTS

1984 No. 1260

CONSUMER PROTECTION

The Cosmetic Products (Safety) Regulations 1984

*Laid before Parliament in draft**Made - - - - - 2nd August 1984**Coming into Operation—
Regulations 1 and 2 28th August 1984**Regulations 3(1), 4 to 6(6),
7 to 8(1)(d) and 8(1)(f) to
11 (except as provided in
Regulation 1(3) and (5)) - 1st January 1986**Regulations 6(7) and
8(1)(e) (except as provi-
ded in Regulation 1(6)) - 1st January 1987**Regulations 3(2) and 12 - 1st January 1988*

Whereas the Secretary of State has, in accordance with section 1(4) of the Consumer Safety Act 1978(a), consulted such organisations as appear to him to be representative of interests substantially affected by these Regulations, such other persons as he considers appropriate and the Health and Safety Commission:

And whereas the Secretary of State has in accordance with section 1(5) of the Consumer Protection Act 1961(b) consulted with such persons and bodies of persons as appear to him requisite:

And whereas the Secretary of State is a Minister designated(c) for the purposes of section 2 of the European Communities Act 1972(d) in relation to measures for safety and consumer protection as respects cosmetic products and any provisions concerning the composition, labelling, marketing, classification or description of cosmetic products and in relation to indication of origin on imported goods:

And whereas a draft of these Regulations has been approved by a resolution of each House of Parliament pursuant to section 7(7) of the said Act of 1978:

(a) 1978 c.38.
 (b) 1961 c.40.
 (c) S.I. 1972/1811, 1975/1707.
 (d) 1972 c.68.

Now, therefore, the Secretary of State in exercise of powers conferred on him by sections 1 and 2(7) of the said Act of 1978, by sections 1 and 2 of the said Act of 1961 and by section 2 of the said Act of 1972 and of all other powers enabling him in that behalf hereby makes the following Regulations:—

Citation and commencement

1.— (1) These Regulations may be cited as the Cosmetic Products (Safety) Regulations 1984.

(2) This Regulation and Regulation 2 shall come into operation on 28th August 1984.

(3) Regulation 3(1) shall come into operation—

(a) in relation to the sale or possession for sale of cosmetic products by the manufacturer or importer into Great Britain or, in the case of cosmetic products manufactured or imported into Great Britain on behalf of another person, by that other person, on 1st January 1986, except where the cosmetic products are sold, or held in possession for sale, by retail, in which case it shall come into operation on 1st January 1988; and

(b) in all other cases, on 1st January 1988.

(4) Regulations 3(2) and 12 shall come into operation on 1st January 1988.

(5) Regulations 4 to 6(6), 7 to 8(1)(d) and 8(1)(f) to 11 shall come into operation—

(a) in relation to the supply, offering to supply, agreeing to supply, exposing for supply or possessing for supply of cosmetic products by the manufacturer or importer into the United Kingdom or, in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person, on 1st January 1986, except where the cosmetic products are supplied, agreed to be supplied, exposed for supply or possessed for supply, by retail, in which case they shall come into operation on 1st January 1988; and

(b) in all other cases, on 1st January 1988.

(6) Regulations 6(7) and 8(1)(e) shall come into operation—

(a) in relation to the supply, offering to supply, agreeing to supply, exposing for supply or possessing for supply of cosmetic products by the manufacturer or importer into the United Kingdom, or in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person, on 1st January 1987, except where the cosmetic products are supplied, agreed to be supplied, exposed for supply or possessed for supply, by retail, in which case they shall come into operation on 1st January 1989; and

(b) in all other cases, on 1st January 1989.

Revocations, modifications and transitional provisions

2. The Cosmetic Products Regulations 1978(a) are hereby amended by the insertion, after Regulation 2, of the following Regulation—

“2A. These Regulations shall not apply in relation to the sale or possession for sale of cosmetic products which satisfy the requirements of the Cosmetic Products (Safety) Regulations 1984, notwithstanding that only Regulations 1 and 2 of those Regulations are in operation.”

3.— (1) The Cosmetic Products Regulations 1978 (other than Regulation 9) and the Cosmetic Products (Amendment) Regulations 1983(b) are hereby revoked.

(2) Regulation 9 of the Cosmetic Products Regulations 1978 is hereby revoked.

Interpretation

4.— (1) In these Regulations—

“the Directive” means Council Directive No. 76/768/EEC(c) as amended by Council Directive No. 82/368/EEC(d), Commission Directive No. 82/147/EEC(e), Commission Directive No. 83/191/EEC(f), Commission Directive No. 83/341/EEC(g), Council Directive No. 83/574/EEC(h) and Commission Directive No. 83/496/EEC(i);

“cosmetic product” means any substance or preparation intended to be applied to any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or to the teeth or buccal mucosa wholly or mainly for the purpose of cleaning, perfuming or protecting them or keeping them in good condition or changing their appearance or combating body odour or perspiration except where such cleaning, perfuming, protecting, keeping, changing or combating is wholly for the purpose of treating or preventing disease;

“cosmetic product intended to come into contact with the mucous membranes” means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin;

“market research experiment” means any activities conducted for the purpose of ascertaining the opinion of persons of—

(a) any cosmetic product; or

(b) anything in, on or with which the cosmetic product is supplied; or

(a) S.I. 1978/1354, amended by S.I. 1983/1477.

(b) S.I. 1983/1477.

(c) O.J. No. L262, 27.9.76, p.169.

(d) O.J. No. L167, 15.6.82, p.1.

(e) O.J. No. L63, 6.3.82, p.26.

(f) O.J. No. L109, 26.4.83, p.25.

(g) O.J. No. L188, 13.7.83, p.15.

(h) O.J. No. L332, 28.11.83, p.38.

(i) O.J. No. L275, 8.10.83, p.20.

- (c) the appearance or any other characteristic of the cosmetic product or any such thing; or
- (d) the name or description under which the cosmetic product is supplied.

A cosmetic product is not the subject of a market research experiment unless—

- (a) any person to whom a cosmetic product is supplied in the course of the experiment is informed, at or before the time at which it is supplied to him, that it is supplied for the purpose of a market research experiment and
- (b) no consideration in money or money's worth is given by such a person for the cosmetic product or any other cosmetic product supplied to him for comparison.

“preservative” means a substance which is added to a cosmetic product for the primary purpose of inhibiting the development of micro-organisms in that product;

“UV filter” means a substance which is added to a sunscreen cosmetic product for the primary purpose of filtering ultra violet rays for the purpose of protecting the epidermis of the user from harmful effects of such ultra violet rays.

(2) References in these Regulations to Schedules are references to the Schedules to these Regulations.

General Requirements

5.— (1) Subject to paragraph (2) below, a cosmetic product shall not be liable to cause damage to human health when it is applied under normal conditions of use.

(2) For the purposes of Regulation 10 below, paragraph (1) above shall apply only to the supply, offering to supply, agreeing to supply, exposing for supply or possessing for supply by the manufacturer or importer into the United Kingdom or, in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person.

Particular requirements

6.— (1) The following provisions of this Regulation are without prejudice to Regulation 5 above and are subject to Regulation 7 below.

(2) A cosmetic product shall not contain any substance listed in Schedule 1:

Provided that no account shall be taken of any such substance which is present only as a trace which could not reasonably have been removed during or after manufacture.

(3) A cosmetic product shall not contain any substance listed in column 2 of Schedule 2 unless the matters specified in columns 3, 4, and 5 of that Schedule in relation to that substance are complied with.

(4) A cosmetic product intended to come into contact with the mucous membranes shall not contain—

- (a) any colouring agent listed in Schedule 3 unless the requirements specified in column 2 of that Schedule in relation to that colouring agent are complied with; and
- (b) any colouring agent which is not listed in that Schedule.

(5) A cosmetic product shall not contain any colouring agent which is listed in Schedule 4 unless the product is intended to come into only brief contact with the skin.

(6) A cosmetic product shall not contain—

- (a) any preservative listed in column 2 of Schedule 5 unless the matters specified in columns 3, 4 and 5 of that Schedule in relation to that preservative are complied with; and
- (b) any preservative which is not listed in that Schedule.

(7) A cosmetic product shall not contain—

- (a) any UV filter listed in column 2 of Schedule 6 unless the matters specified in columns 3 and 4 of that Schedule in relation to that UV filter are complied with; and
- (b) any UV filter which is not listed in that Schedule

7.—(1) The Secretary of State may by way of exemption from the provisions of these Regulations authorise the use of a particular substance in a cosmetic product.

(2) In giving an authorisation the Secretary of State may impose conditions relating to the use of a particular substance in a cosmetic product. The conditions may relate to any matter which the Secretary of State considers appropriate including—

- (a) the purpose of the substance;
- (b) the type of cosmetic product;
- (c) the maximum concentration of the substance in any cosmetic product; and
- (d) information and marking requirements.

(3) The Secretary of State may on reasonable notice vary or revoke any authorisation given under paragraph (1) above.

(4) On giving, varying or revoking an authorisation, the Secretary of State shall arrange for the authorisation, variation or revocation, as the case may be, to be published in such manner as he considers appropriate for bringing it to the attention of persons who, in his opinion, would be likely to have an interest in it.

(5) No person shall be convicted of an offence under section 2 of the Consumer Safety Act 1978 by reason of a cosmetic product's containing a particular substance provided that at the time when but for this Regulation an offence would have been committed—

- (a) the use of that particular substance in that cosmetic product was duly authorised; and
- (b) all of the conditions imposed by the authorisation were complied with.

Marking

8.— (1) Subject to the following provisions of this Regulation, the container or the outer packaging (if any) in which a cosmetic product is supplied, offered to be supplied, agreed to be supplied, exposed for supply or possessed for supply or delivered pursuant to any supply, or a label affixed to the product, the container or the outer packaging, shall bear the following particulars:—

- (a) the name or trade name and the address or registered office of the manufacturer of the product or of a supplier thereof, being a manufacturer or supplier established within a Member State of the European Economic Community;
- (b) in the case of a cosmetic product likely within 30 months from the manufacture thereof to cease either to comply with the requirements of Regulation 5 above or to fulfil the purpose for which it was intended, the words 'Best before . . . ' immediately followed by
 - (i) the earliest date on which it is likely to so cease; or
 - (ii) an indication of where that date appears on the labellingand any particular precautions to be observed to ensure that the product does not so cease before that date.
- (c) in the case of a cosmetic product containing a substance listed in column 2 of Schedule 2, the information specified in column 6 of that Schedule in relation to that substance;
- (d) in the case of a cosmetic product containing a preservative listed in column 2 of Schedule 5, the information specified in column 6 of that Schedule in relation to that preservative;
- (e) in the case of a cosmetic product containing a UV filter listed in column 2 of Schedule 6, the information specified in column 5 of that Schedule in relation to that UV filter;
- (f) any particular precautions to be observed in use (not being precautions included in the information referred to in sub-paragraphs (b), (c), (d) and (e) above);
- (g) a means of identifying the batch in which the product was manufactured (or, if the product was not manufactured in a batch, a reference from which the date and place of manufacture can be identified):

Provided that the requirements specified in sub-paragraphs (b) and (g) above need not be complied with in relation to a cosmetic product which is the subject of a market research experiment.

(2) The particulars referred to in sub-paragraphs (a) to (f) of paragraph (1) above shall be in lettering which is visible, indelible and easily legible; and the particulars referred to in sub-paragraph (g) of that paragraph shall be indelible.

(3) The particulars referred to in sub-paragraph (a) of paragraph (1) above may be abbreviated if such abbreviation does not prevent the person concerned from being identified.

(4) The date referred to in sub-paragraph (b) of paragraph (1) above shall include the month and the year, and the month shall precede the year.

(5) The particulars referred to in sub-paragraphs (b) to (f) of paragraph (1) above shall be in the English language; but this shall not prohibit the additional use of other languages.

(6) The particulars referred to in sub-paragraphs (c) to (f) of paragraph (1) above shall appear on the container or on a label attached thereto: provided that where—

- (a) it is impracticable by reason of the size or shape of the container for the said particulars so to appear and the container is enclosed in outer packaging, or
- (b) two or more products are supplied, offered or agreed to be supplied or exposed or possessed for supply together as a single item, each product being in a separate container and the containers being enclosed together in outer packaging which bears clear and conspicuous instructions to the effect that the product must be mixed together in specified proportions before use,

the said particulars may appear on the outer packaging or on a label attached thereto or on a leaflet enclosed in the outer packaging (and, in the case of a leaflet, an indication shall appear on the container referring to the information in the leaflet).

(7) Where it is impracticable, for reasons of size, for the particulars referred to in sub-paragraph (g) of paragraph (1) above to appear on the container or outer packaging or on a label attached to either thereof, the said particulars shall appear on the packaging in which the product is exposed for supply.

(8) In the case of a supply of soap which is not in a container, either the soap itself or the packaging in which it is exposed for supply or the container in which it was last contained before the supply shall bear the particulars referred to in sub-paragraph (a) and (g) of paragraph (1) above, and in so far as any of the particulars referred to in sub-paragraphs (b) to (f) of paragraph (1) above are required they shall appear on a leaflet which shall be delivered to the buyer with the soap; and where either of the particulars referred to in sub-paragraph (a) and (g) of paragraph (1) above appears on the soap itself the requirement of indelibility shall apply only until it has been put into use.

Enforcement

9.— (1) No proceedings for a contravention of Regulation 5 shall be begun in England or Wales except by or with the consent of the Secretary of State or the Director of Public Prosecutions and in Northern Ireland except by or with the consent of the Secretary of State or the Director of Public Prosecutions for Northern Ireland.

(2) Regulations 5, 6 and 8 above do not apply in any case in which the person supplying the cosmetic product, offering or agreeing to supply the cosmetic product or exposing or possessing the cosmetic product for supply reasonably believes that it will not be used in a Member State of the European Economic Community.

(3) Regulation 8(5) does not apply in any case in which the person supplying the cosmetic product, offering or agreeing to supply the cosmetic product or exposing or possessing the cosmetic product for supply reasonably believes that it will not be used in the United Kingdom.

10. Subject to Regulations 7 and 9(2) and (3) above, no person shall supply, offer to supply, agree to supply, expose for supply or possess for supply any cosmetic product in respect of which the requirements of Regulations 5, 6 and 8 above are not satisfied.

11. Any test of goods seized or purchased by or on behalf of an enforcement authority in pursuance of Schedule 2 to the Consumer Safety Act 1978 (which relates to the enforcement of Regulations) for the purpose of ascertaining whether the provisions of these Regulations have been contravened or are being complied with shall in all cases be carried out in accordance with the provisions of paragraphs 2 to 5 of Schedule 7 and any test for which a method is specified in paragraph 6 of that Schedule shall be carried out in accordance with that method.

Modification of Trade Descriptions Act 1972

12. Nothing in the Trade Descriptions Act 1972(a) shall require a United Kingdom name or mark as therein defined applied to any cosmetic product to be accompanied by an indication of the country in which that cosmetic product was manufactured or produced if the United Kingdom name or mark is the name, address or trade mark of the person responsible for marketing the cosmetic product and the cosmetic product was manufactured or produced in a Member State of the European Economic Community.

2nd August 1984.

Alexander Fletcher,
Parliamentary Under-Secretary of State,
Department of Trade and Industry.

(a) 1972 c.34.

SCHEDULE 1

Regulation 6(2)

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

The alphabetical list set out in column 2 of this Schedule contains one or more of the names of each of the substances referred to in Regulation 6(2); in certain cases a name is given of 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 that 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 Directive, from which this Schedule is derived.

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
1	Acenocoumarol	3	254
2	3-(α -Acetonylbenzyl)-4-hydroxycoumarin and its salts	354, 668	203
3	3-(α -Acetonyl- <i>p</i> -nitrobenzyl)-4-hydroxycoumarin	1	254
4	2-(or β -)Acetoxyethyltrimethylammonium hydroxide and its salts	6	2
5	2-Acetylamino-5-chlorobenzoxazole	144	1
6	Acetylcholine and its salts	4	2
7	Acetylene chlorides	215	126
8	Acetylenic alcohols, their esters, ethers and salts	16	16
8A	Acetylethyltetramethyltetralin (AETT)	300A	362
9	β -(7 α -Acetylthio-17 β -hydroxy-3-oxoandrost-4-en-17 α -yl)propionic acid lactone	569	4
10	Aconitine and its salts	—	12
11	<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)	—	11
12	<i>Adonis vernalis</i> L. and its preparations	—	13
13	Adrenaline	236, 279	14
14	Alkali pentacyanonitrosylferrate (2-)	534-5, 564-5	255
15	<i>O</i> -Alkyldithiocarbonic acids, salts of	669	336
16	Alkyne alcohols, their esters, ethers and salts	8	16
17	Alloclamide and its salts	21	19
18	Allyl isothiocyanate	—	18

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
19	2-(4-Allyl-2-methoxyphenoxy)- <i>N,N</i> -diethylacetamide and its salts	—	224
20	<i>N</i> -Allylnormorphine, its salts and ethers	435	20
21	2-Allyloxy-4-chloro- <i>N</i> -(2'-diethylaminoethyl)benzamide and its salts	17	19
22	Alypine and its salts	42, 97	143
23	Ambenonium chloride	(467)	132
24	4-(or <i>p</i> -)Aminobenzoic acid esters except glycerol 1-(4-aminobenzoate))	—	167
25	2-Amino-1,2-bis(4-methoxyphenyl) ethanol and its salts	—	29
26	3-Amino-4-butoxybenzoic acid 2-diethylaminoethyl ester and its salts	89,222	23
27	Aminocaproic acid and its salts	31	7
28	2-Amino-5-chlorobenzoxazole	674	24
29	4-Amino- <i>N</i> -(2'-diethylaminoethyl) benzamide, its salts and derivatives	537	23
30	Aminoheptane, its isomers and salts	659	27
31	6-Aminohexanoic acid and its salts	27	7
32	α -(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	458, 459	257
33	4-Amino- <i>N</i> ¹⁰ -methylfolic acid	406	6
34	2-Amino-6-methylheptane and its salts	371, 464	28
35	2-Amino-4-methylhexane and its salts	252, 419	30
36	4-(or <i>p</i> -)Aminosalicylic acid and its salts	—	31
37	Aminotoluenes, their isomers, salts and halogenated and sulphonated derivatives	631	32
38	Aminoxylenes, their isomers, salts and halogenated and sulphonated derivatives	671	33
39	Amitriptyline and its salts	249	146
40	<i>Ammi majus</i> and its galenical preparations	—	35
41	Amphetamine, its salts and derivatives and salts of those derivatives	(595)	21
42	Amydracaine and its salts	22, 97	143
43	Amylene chloride	216	36

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
44	Amyl nitrites	—	247
45	Amylobarbitone and its salts	(63)	220
46	Amylocaine and its salts	247	50
47	<i>Anamirta cocculus</i> L. (fruit)	—	106
48	Substances with androgenic effect	—	37
49	Aniline, its salts and halogenated and sulphonated derivatives	—	22
50	Anthracene oil	—	38
51	Antibiotics (except tyrothricin)	—	39
52	Antimony and its compounds	—	40
53	<i>Apocynum cannabinum</i> L. and its preparations	—	41
54	Apomorphine and its salts	610	42
55	Apronalide	374	216
56	Arecoline	427	238
57	Arsenic and its compounds	—	43
58	<i>Atropa belladonna</i> L. and its compounds	—	44
59	Atropine, its salts and derivatives	—	45
60	Azacyclonol and its salts	270	286
61	Azamethonium bromide	(420)	121
62	Barbitone and its salts	(63)	220
63	Barbiturates	various	220
64	Barium salts (except barium sulphate, barium sulphide under the condition laid down in Part I of Schedule 2, for alkaline earth sulphides and lakes, salts and pigments prepared from those colouring agents identified in Column 1 of Schedule 3 by "B" immediately after the name or colour index number)	—	46
65	Bemegride and its salts	295, 296	183
66	Benactyzine	223	157
67	Bendrofluazide and its derivatives	68, 81	53
68	Bendroflumethiazide and its derivatives	67, 81	53
69	Benzamine and its salts	653	51
70	Benzatropine and its salts	266	158
71	Benzazepines, their salts and derivatives	—	49

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
72	Benzene	—	47
73	2-Benzhydryloxyethyl dimethylamine and its salts	261	339
74	Benzidine	209	26
75	Benzilium bromide	84	60
76	2-Benziloyloxymethyl-1,1-dimethylpyrrolidinium methylsulphate	532	239
77	Benzimidazolone	78, 232	48
78	Benzimidazol-2(3 <i>H</i>)-one	77	48
79	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol (except natural content of essences)	180	357
80	Benzodiazepines, their salts and derivatives	—	49
81	Benzothiadiazine and its derivatives	67, 68	53
82	3-(<i>N</i> -Benzylhydrazinocarbonyl)-5-methylisoxazole	368	52
83	Benzylideneacetone	502	356
84	3-Benzylloxy-1,1-diethylpyrrolidine hydrobromide	75	60
85	<i>p</i> -Benzylloxyphenol	348, 431	178
86	2-[Benzyl- <i>N</i> -(2-pyridyl)amino]-ethyl dimethylamine	552, 656	347
87	Beryllium and its compounds	—	54
88	Betamethasone	(320)	300
89	Betoxycaine and its salts	26, 222	23
90	BHC (gamma-BHC)	329, 331, 382	195
91	Bietamiverine	226	287
92	1,6-Bis(2-chloroethylamino)-1,6-dideoxymannitol and its salts	390	89
93	2-[Bis(2-chloroethyl)amino]-1-oxa-3-aza-2-phosphacyclohexane 2-oxide and its salts	96, 200	88
94	<i>N,N</i> -Bis(2-chloroethyl)methylamine and its salts	141, 433	87
95	<i>N,N</i> -Bis(2-chloroethyl)methylamine <i>N</i> -oxide and its salts	434	86
96	<i>N,N</i> -Bis(2-chloroethyl)- <i>N',O</i> -propylenephosphoramidic anhydride and its salts	93, 200	88
97	1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts	22, 42	143

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
98	2,2-Bis(hydroxymethyl)butan-1-ol trinitrate	543	206
99	2,6-Bis(β -hydroxyphenethyl)-1-methylpiperidine and its salts	384	219
100	Bithionol	620	352
101	Bretilium tosilate (or tosylate)	104	56
102	Bromine, elemental	—	55
103	Bromisoval	107	58
104	<i>p</i> -Bromobenzylethyldimethylammonium <i>p</i> -toluenesulphonate	101	56
105	Bromodiethylacetylurea	106, 132	57
106	α -Bromo- α -ethylbutyrylurea	105, 132	57
107	Bromoisovalerylurea	103	58
108	1- <i>p</i> -bromophenyl-1-(2-pyridyl)-3-dimethylaminopropane and its salts	109	59
109	Brompheniramine and its salts	108	59
110	Brucine	—	62
111	Butanilicaine and its salts	416	90
112	Butobarbitone and its salts	(63)	220
113	Butopirine and its salts	115	288
114	2-Butoxy- <i>N</i> -(2-diethylaminoethyl)cinchoninamide and its salts	170	129
115	2-Butoxyethyl α -phenyl- α -(<i>N</i> -piperidyl)acetate and its salts	113	288
116	1-Butyl-3-(<i>N</i> -crotonoylsulphanilyl)urea	—	108
117	4-Butyl-1,2-diphenylpyrazolidine-3,5-dione	501	67
118	4-Butyl-1-phenylpyrazolidine-3,5-dione	430	64
119	1-Butyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	630	65
120	1-Butyl-3-sulphanilylurea	133	66
121	4-Butylthiobenzohydryl dimethylaminoethyl sulphide	126	140
122	Cadmium and its compounds	—	68
123	Calabar bean	521	281
124	Cantharides, <i>Cantharis vesicatoria</i>	567	69
125	Cantharidin	336	70
126	Captodiamine	121	140
127	Caramiphen and its salts	505	169

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
128	<i>N</i> -(3-Carbamoyl-3,3-diphenylpropyl)- <i>N,N</i> -diisopropylmethylammonium salts	373	156
129	Carbazole, nitroderivatives of	451	72
130	Carbon disulphide	—	73
131	Carbon tetrachloride	606	315
132	Carbromal	105, 106	57
133	Carbutamide	120	66
134	Carisoprodol	425	235
135	Catalase	—	74
136	Cephaeline and its salts	—	75
137	<i>Chenopodium ambrosioides</i> (essential oil)	—	76
138	Cherry laurel water	548	291
139	Chloral hydrate	644	77
140	Chlorine	—	78
141	Chlormethine and its salts	94, 433	87
142	Chlormezanone	154	91
143	5-Chlorobenzoxazolinone	165	82
144	<i>N</i> -5-Chlorobenzoxazol-2-ylacetamide	5	1
145	2-Chloro-4-dimethylamino-6-methylpyrimidine	149, 185	83
146	2-Chloro-9-(α -dimethylamino-propylidene)thioxanthene (<i>trans</i> -form) and its salts	162	84
147	4-Chloro-1,3-disulphamoylbenzene	173	85
148	Chloroethane	289	96
148A	Chloroform	645A	—
149	2-Chloro-6-methylpyrimidin-4-yl-dimethylamine	145, 185	83
150	Chlorophacinone	155	93
151	1-(<i>p</i> -Chloro- α -phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	357	240
152	4-[4-(4-Chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	328	185
153	2-(4-Chlorophenyl)-3-methylbutane-2,3-diol	490	95
154	2-(4-Chlorophenyl)-3-methyl-4-metathiazonone-1,1-dioxide	142	91
155	2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan-1,3-dione	150	93

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
156	1-(4-Chlorophenyl)-1-phenyl-1-dimethylaminoethoxyethane	159	94
157	Chloropicrine	—	325
158	3-(4-Chloro-3-sulphamoylphenyl)-3-hydroxyisoindolin-1-one	163, 164	262
159	Chlorphenoxamine	156	94
160	Chlorpromazine	(496)	320
161	Chlorpropamide	544	79
162	Chlorprothixene and its salts	146	84
163	Chlortalidone	158, 164	262
164	Chlorthalidone	158, 163	262
165	Chlorzoxazone	143	82
166	Cholecalciferol	(667)	335
167	Choline salts and their esters	—	168
168	Chromium, chromic acid and salts of the acid	—	97
169	Chrysoidine citrate hydrochloride	500	81
170	Cinchocaine and its salts	114	129
171	Cincophen, its salts and derivatives and salts of those derivatives	513	8
172	<i>Claviceps purpurea Tul.</i> , its alkaloids and galenical preparations	281	98
173	Clofenamide	147	85
174	Clofenotane	202, 643	123
175	Cobalt benzenesulphonate	—	101
176	Cocculin	523	282
177	Colchicine, its salts and derivatives	—	102
178	Colchicoside and its derivatives	—	103
179	<i>Colchicum autumnale L.</i> and its galenical preparations	—	104
180	Coniferyl benzoate (except natural content of essences)	79	357
181	Coniine	545	290
182	<i>Conium maculatum L.</i> (fruit, powder, galenical preparations)	—	99
183	Convallatoxin	—	105
184	Coumetarol	408	225
185	Crimidine	145, 149	83
186	<i>Croton tiglium</i> (oil)	—	107
187	Curare and curarine	—	109

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
188	Curarizants, synthetic	—	110
189	Cyanides	345, 347	111
190	1-(3-Cyano-3,3-diphenylpropyl)-4-phenyl-4-piperidinecarboxylic acid ethyl ester hydrochloride	262	80
191	Cyclarbamate	199	122
192	Cyclizine and its salts	267	159
193	Cyclobarbitone and its salts	(63)	220
194	Cyclocoumarol	233	234
195	2- α -Cyclohexylbenzyl(<i>N,N,N',N'</i> -tetraethyl)trimethylenediamine	491	112
196	2-Cyclohexyl-3,5-dimethylphenol and its salts	198	113
197	1-Cyclohexyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	323	100
198	Cyclomenol and its salts	196	113
199	Cyclopentane-1,1-dimethanol dicarbanilate	191	122
200	Cyclophosphamide and its salts	93, 96	88
201	<i>Datura stramonium L.</i> and its galenical preparations	571	301
202	DDT (<i>p,p'</i> -DDT)	174, 643	123
203	Deanol aceglumate	242	3
204	Decamethonium bromide	205	214
205	Decamethylenebis(trimethylammonium) salts	204	214
206	Dextromethorphan and its salts	409	226
207	Dextropropoxyphene	246	116
208	<i>O,O'</i> -Diacetyl- <i>N</i> -allyl- <i>N</i> -normorphine	—	117
208A	1,2-Diaminobenzene and its salts	507A	363
209	<i>p,p'</i> -Diaminodiphenyl	74	26
210	1,4:3,6-Dianhydrosorbitol 2,5-dinitrate	376	148
211	5-(α,β -Dibromophenethyl)-5-methylhydantoin	—	119
212	Dibromosalicylanilides (except as those impurities of tribromosalicylanilide permitted in accordance with the requirements specified in column 4 of Part II of Schedule 2)	213, 397	351

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
213	Dibromsalan (except as those impurities of tribromosalicylanilide permitted in accordance with the requirements specified in column 4 of Part II of Schedule 2)	(212)	351
214	Dichloroethanes	290, 293	125
215	Dichloroethylenes	7, 666	126
216	2,3-Dichloro-2-methylbutane	43	36
217	Dichlorosalicylanilides	—	349
218	Dicoumarin	219, 417	231
219	Dicoumarol	218, 417	231
220	2-(Diethylaminoethoxy)ethyl α -phenylpiperidine-1-acetate dimethiodide	531	137
221	1-[4-(β -Diethylaminoethoxy)phenyl]-1-(4-tolyl)-2-(4-chlorophenyl)-ethanol	655	92
222	2-Diethylaminoethyl 3-amino-4-butoxybenzoate and its salts	26, 89	23
223	2-Diethylaminoethyl benzilate and its salts	66	157
224	2-Diethylaminoethyl 4-ethoxybenzoate and its salts	364, 474	179
225	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	—	128
226	2-Diethylaminoethyl α -phenyl- α -(<i>N</i> -piperidyl)acetate	91	287
227	3-Diethylaminopropyl cinnamate	—	130
228	Diethyl 4-nitrophenyl phosphate	472	170
229	<i>O,O</i> -Diethyl <i>O</i> -4-nitrophenyl phosphorothioate	473	131
230	Difenclozazine	504	270
231	Digitaline and all heterosides of <i>Digitalis purpurea L.</i>	—	134
232	4,5-Dihydrobenzimidazol-4-one	77	48
233	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2 <i>H</i> ,5 <i>H</i> -pyrano [3,2- <i>c</i>]-[1]-benzopyran-5-one	194	234
234	Dihydrotachysterol	—	342
235	3,4-Dihydroxy- α -(isopropylamino-methyl)benzyl alcohol	372, 375	17
236	3,4-Dihydroxy- α -(methylamino-methyl)benzyl alcohol	13, 279	14

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
237	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene)dicoumarin	—	207
238	1-(3,4-Dihydroxyphenyl)-2-ethylaminopropan-1-ol	259	136
239	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihyposulfite	366	361
240	4-[β -(3,4-Dimethoxyphenyl)ethyl]-1-(2-chlorophenyl)piperazine and its salts	392	141
241	Dimethylamine	—	142
242	2-Dimethylaminoethyl <i>N</i> -acetylglutamate	203	3
243	2-[α -(2-Dimethylaminoethoxy)- α -methylbenzyl]pyridine and its salts	275	176
244	2-Dimethylaminoethyl <i>p</i> -butylaminobenzoate and its salts	604	63
245	2-[(2-Dimethylaminoethyl)-2-thenylamino]pyridine and its salts	402	144
246	(+)-4-Dimethylamino-3-methyl-1,2-diphenyl-2-propionyloxybutane	207	116
247	1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts	46	50
248	2-Dimethylaminopropiophenone and its salts	399	145
249	3-(3-Dimethylaminopropylidene)-1,2:4,5-dibenzocyclohepta-1,4-diene and its salts	39	146
250	<i>N,N</i> -Dimethyldiguanide and its salts	401	147
251	Dimethylformamide	—	355
252	1,3-Dimethylpentylamine and its salts	35, 419	30
253	1,2-Dimethyl-4-phenyl-4-carbomethoxyhexamethyleneimine and its salts	403	174
254	1,3-Dimethyl-4-phenyl-4-carboxyethylhexamethyleneimine and its salts	400	171
255	Dimethyl sulphoxide	—	338
256	Dimevamide and its salts	263	153
257	Dinitrophenol isomers	—	151
258	Dioxane	—	343
259	Dioxethedrin and its salts	238	136
260	2,5-Dioxo-3,3-diethyl-5-methylpiperidine and its salts	428	133

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
261	Diphenhydramine and its salts	73	339
262	Diphenoxylate hydrochloride	190	80
263	2,2-Diphenyl-4-dimethylamino-valeramide and its salts	256	153
264	5,5-Diphenyl-4-imidazolidone	—	160
265	4-Diphenylmethoxy-1-methylpiperidine and its salts	271	154
266	3-Diphenylmethoxytropane and its salts	70	158
267	1-Diphenylmethyl-4-methylpiperazine	192	159
268	1,2-Diphenyl-4-(2-phenylsulphinylethyl)pyrazolidine-3,5-dione	578	155
269	α,α -Diphenyl-2-piperidinemethanol	530	285
270	α,α -Diphenyl-4-piperidinemethanol	60	286
271	Diphenylpyraline and its salts	265	154
272	2,5-Dipropoxy-3,6-bis(ethyleneimino)-1,4-benzoquinone	363	152
273	4-Dipropylsulphamylbenzoic acid	536	161
274	Disulfiram	614, 625	162
275	Doxylamine and its salts	243	176
276	Emetine, its salts and derivatives	—	163
277	Endrin	332	196
278	Ephedrine and its salts	—	164
279	Epinephrine	13, 236	14
280	Ergocalciferol	(667)	335
281	Ergot, its alkaloids and galenical preparations	172	98
282	Eserine and its salts	522	166
283	Ethionamide	294	319
284	Ethoheptazine and its salts	423	173
285	Ethopropazine and its salts	(496)	320
286	2-Ethylamino-5-phenyloxazolin-4-one	302	180
287	Ethyl bis(4-hydroxycoumarinyl)acetate and salts of the acid	288	204
288	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	287	204
289	Ethyl chloride	148	96
290	Ethylene dichloride	214	125
291	Ethylene oxide	—	182

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
292	2-Ethyl-2,3-epoxyhexamide and its derivatives	468	165
293	Ethylidene chloride	214	125
294	3-Ethylisothionicotinamide	283	319
295	β -Ethyl- β -methylglutarimide and its salts	65, 296	183
296	4-Ethyl-4-methylpiperidine-2,6-dione and its salts	65, 295	183
297	β -Ethyl- β -methylvaleramide	662	184
298	Ethylphenacemide	503	272
299	2-Ethyl-2-phenylglutarimide and its salts	300, 321	181
300	3-Ethyl-3-phenylpiperidine-2,6-dione and its salts	299, 321	181
300A	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetoneaphthone	8A	362
301	Fenadiazole	356	208
302	Fenozolone	286	180
303	Fenramidol	512, 515	274
304	Fluanisone	309	187
305	Fluoresone	308	189
306	4'-Fluoro-4-[4-hydroxy-4-(α,α,α -trifluoro- <i>m</i> -tolyl)piperidino]-butyrophenone	650	188
307	6 α -Fluoro-16 α -methyl-11 β ,17 α ,21-trihydroxypregna-1,4-diene-3,20-dione	471	186
308	<i>p</i> -Fluorophenylethylsulphone	305	189
309	1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)-1-piperazinyl]-butan-1-one	304	187
310	5-Fluoropyrimidine-2,4-dione	311	190
311	Fluorouracil	310	190
312	Fluphenazine	(496)	320
313	Furazolidone	454	252
314	Furfuryltrimethylammonium salts	317	192
315	Furo[3,2- <i>g</i>]chromen-7-one and its alkyl-substituted derivatives (except natural content of essences)	316, 412, 654	358
316	Furocoumarin and its alkyl-substituted derivatives (except natural content of essences)	315, 412, 654	358

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
317	Furtrethonium iodide	314	192
318	Galantamine	—	193
319	Gallamine triethiodide	657	329
320	Glucocorticoids	88	300
321	Glutethimide and its salts	299, 300	181
322	Glycerol trinitrate	455, 542	253
323	Glycyclamide	197	100
324	Gold salts	—	296
325	Guaifenesin	410	230
326	Guanethidine and its salts	327	259
327	<i>N</i> -(2-Guanidinoethyl)heptamethyleimine and its salts	326	259
328	Haloperidol	152	185
329	HCH (gamma-HCH)	90, 331, 382	195
330	HETP	335	316
331	1,2,3,4,5,6-Hexachlorocyclohexane	90, 329, 382	195
332	(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	277	196
333	Hexachloroethane	—	197
334	(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	369	198
335	Hexaethyl tetraphosphate	330	316
336	(1 <i>R</i> , 2 <i>S</i>)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride	125	70
337	(3 <i>S</i> , 5 <i>aR</i> , 9 <i>bS</i>)-3,3a,4,5,5a,9b-Hexahydro-3,5a,9-trimethylnaphtho-[1,2- <i>b</i>]furan-2,8-dione	557	217
338	Hexamethonium bromide	(339)	124
339	<i>N,N'</i> -Hexamethylenebis(trimethylammonium) salts	338	124
340	Hexapropymate	546	115
341	Hydrastine, hydrastinine and their salts	—	199
342	Hydrazides and their salts	—	200
343	Hydrazine, its derivatives and their salts	—	201
344	2-Hydrazino-octane and its salts	462	202
345	Hydrocyanic acid and its salts	189, 347	111

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
346	Hydrofluoric acid, its normal salts, complexes and hydrofluorides (except those listed in part I of Schedule 2)	—	191
347	Hydrogen cyanide and its salts	189, 345	111
348	Hydroquinone monobenzyl ether	85, 431	178
349	7-[2-Hydroxy-3-(2-hydroxyethyl- <i>N</i> -methylamino)propyl]theophylline	670	135
350	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts	651	5
351	3-[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propionic acid and its salts	628	9
352	1-Hydroxymethyl-1-cyclohexylacetic acid, sodium salt	563	114
353	8-Hydroxy-5(or 6)-nitroquinoline and its salts	457	209
354	4-Hydroxy-3-(3-oxo-1-phenylbutyl)-coumarin and its salts	2, 668	203
355	1-(4-Hydroxy- β -phenylethyl)-4-phenyl-4-carbethoxypiperidine and its salts	470	172
356	2-(4-Hydroxyphenyl)-1,3,4-oxadiazole	301	208
356A	1-Hydroxy-2,4,6-trinitrobenzene	522A, 653A	268
357	Hydroxyzine	151	240
358	Hyoscine, its salts and derivatives	560	295
359	Hyoscyamine, its salts and derivatives	—	210
360	<i>Hyoscyamus niger L</i> (leaves, seeds powder and galenical preparations)	—	211
361	2-Imino-5-phenyloxazolidin-4-one and its salts	476	212
362	Imperatorin	415	34
363	Inproquone	272	152
364	Intracaine and its salts	224, 474	179
365	Iodine	—	213
366	Iodothymol	239	361
367	Ipecacuanha (<i>Cephaelis ipecacuanha Brot.</i> and related species) (roots, powder and galenical preparations)	—	215
368	Isocarboxazid	82	52
369	Isodrin	334	198
370	Isometheptene and its salts	413	228
371	2-Isooctylamine and its salts	34, 464	28

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
372	Isoprenaline	235, 375	17
373	Isopropamide iodide	128	156
374	(2-Isopropylpent-4-enoyl)urea	55	216
375	Isoproterenol	235, 372	17
376	Isosorbide dinitrate	210	148
377	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	—	294
378	Laurel oil	379	359
379	<i>Lurus nobilis</i> L. (oil from seeds)	378	359
380	Lead and its compounds (except lead acetate)	—	289
381	Levopropacetoperane and its salts	528	284
382	Lindane	90, 329, 331	195
383	<i>Lobelia inflata</i> L. and its galenical preparations	—	218
384	Lobeline and its salts	99	219
385	LSD	387, 388	127
386	Lupinidine and its salts	568	299
387	Lysergic acid diethylamide and its salts	385, 388	127
388	Lysergide and its salts	385, 387	127
389	Malononitrile	—	149
390	Mannomustine and its salts	92	89
391	Mecamylamine	613	229
392	Mefeclozazine and its salts	240	141
393	Mephesisin and its esters	633	322
394	Meprobamate	426	236
395	Mercury and its compounds (except those listed in Part III of Schedule 2 or in Part II of Schedule 5)	—	221
396	Mescaline and its salts	652	222
397	Metabromsalan (except as those impurities of tribromosalicylanilide permitted in accordance with the requirements specified in column 4 of Part II of Schedule 2)	212	351
398	Metaldehyde	533	223
399	Metamfepramone and its salts	248	145
400	Metethoheptazine and its salts	254	171

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
401	Metformin and its salts	250	147
402	Methapyrilene and its salts	245	144
403	Metheptazine and its salts	253	174
404	Methocarbamol	411	205
405	Methohexitone and its salts	(63)	220
406	Methotrexate	33	6
407	2-[4-Methoxybenzyl- <i>N</i> -(2-pyridyl)amino]ethyl dimethylamine maleate	551	346
408	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	184	225
409	(+)-3-Methoxy- <i>N</i> -methylmorphinan and its salts	206	226
410	3-(4-Methoxyphenoxy)propane-1,2-diol	325	230
411	3-(2-Methoxyphenoxy)propane-1,2-diol 1-carbamate	404	205
412	8-Methoxypsoralen (except natural content of essences)	315, 316	358
413	6-Methylamino-2-methylhept-2-ene and its salts	370	228
414	2-Methyl-1,2-bis(3-pyridyl)propan-1-one	429	292
415	9-(3-Methylbut-2-enyloxy)furo[3,2- <i>g</i>]chromen-7-one	362	34
416	2-Methyl-6-chloroanilide of <i>n</i> -butylaminoacetic acid and its salts	111	90
416A	1-Methyl-2,4-diamino-benzene and its salts	423A	364
417	3,3-Methylenebis-(4-hydroxycoumarin)	218, 219	231
418	2-Methylheptylamine and its salts	—	227
419	4-Methyl-2-hexylamine and its salts	35, 252	30
420	<i>N,N'</i> -[(Methylimino)diethylene]bis-(ethyl dimethylammonium) salts	61	121
421	1-Methyl-2-mercaptoimidazole	619	233
422	Methylphenidate and its salts	509	175
423	1-Methyl-4-phenyl-4-carbethoxyhexamethyleneimine and its salts	284	173
423A	4-Methyl- <i>m</i> -phenyldiamine and its salts	416A	364
424	3-Methyl-2-phenylmorpholine, its derivatives and salts	493	232

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
425	2-Methyl-2-propyl-1-isopropylcarbamoyloxy-3-carbamoyloxypropane	134	235
426	2-Methyl-2-propylpropane-1,3-diol dicarbamate	394	236
427	<i>N</i> -Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester	56	238
428	Methyprylon and its salts	260	133
429	Metyrapone	414	292
430	Mofebutazone	118	64
431	Monobenzone	85, 348	178
432	Morpholine and its salts	—	344
433	Mustine and its salts	94, 141	87
434	Mustine <i>N</i> -oxide and its salts	95	86
435	Nalorphine, its salts and ethers	20	20
436	Naphazoline and its salts	442	244
437	2-Naphthol	438	241
438	β -Naphthol	437	241
439	1- and 2-Naphthylamines and their salts	440	242
440	α - and β -Naphthylamines and their salts	439	242
441	3-(1-Naphthyl)-4-hydroxycoumarin	—	243
442	2-(1-Naphthylmethyl)imidazoline and its salts	436	244
443	Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on Narcotic Drugs 1961 (Treaty Series No. 34 (1965), Cmnd. 2631)	—	306
444	Narcotine and its salts	460	258
445	Neodymium and its salts	—	309
446	Neostigmine and its salts	—	245
447	Nicotine and its salts	—	246
448	Nitrites, inorganic (except sodium nitrite)	—	248
449	Nitrobenzene	—	249
450	Nitrocresols and their alkali metal salts	—	250
451	Nitroderivatives of carbazole	129	72
452	Nitrofurantoin	453	251
453	<i>N</i> -(5-Nitro-2-furfurylidene)-1-aminohydantoin	452	251

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
454	3-(5-Nitrofurfurylideneamino)-oxazolidin-2-one	313	252
455	Nitroglycerine	322, 542	253
456	Nitrostilbenes, their homologues and derivatives	—	256
457	Nitroxoline and its salts	353	209
458	Noradrenaline and its salts	32, 459	257
459	Norepinephrine and its salts	32, 458	257
460	Noscapine and its salts	444	258
461	Nux vomica and its preparations	575	305
462	Octamoxin and its salts	344	202
463	Octamylamine and its salts	484	267
464	Octodrine and its salts	34, 371	28
465	Oestrogens (except oestradiol, oestriol and oestrone)	—	260
466	Oleandrin	—	261
467	[Oxalybis(iminoethylene)]bis-[(<i>o</i> -chlorobenzyl)diethylammonium] salts	23	132
468	Oxamide and its derivatives	292	165
469	2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-11 <i>b</i> <i>H</i> -benzo-[<i>a</i>]quinoline and its salts	602	139
470	Oxpheneridine and its salts	355	172
471	Paramethasone	307	186
472	Paraoxon	228	170
473	Parathion	229	131
474	Parethoxycaine and its salts	224, 364	179
475	Pelletierine and its salts	529	263
476	Pemoline and its salts	361	212
477	Pentachloroethane	—	264
478	Pentaerythritol chloral	488	266
479	Pentaerythritol tetranitrate	480, 487	265
480	Pentaerythrityl tetranitrate	479, 487	265
481	Pentamethonium bromide	482	120
482	<i>N,N'</i> -Pentamethylenebis-(trimethylammonium) salts	481	120
483	Pentobarbitone and its salts	(63)	220
484	Pentylaminomethylheptane, its isomers and salts	463	267

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
485	Perchloroethylene	605	314
486	Perphenazine and its salts	(496)	320
487	PETN	479, 480	265
488	Petrichloral	478	266
489	Phenacemide	499	269
490	Phenaglycodol	153	95
491	Phenetamine	195	112
492	Phenindione	508	271
493	Phenmetrazine, its derivatives and salts	424	232
494	Phenobarbitone and its salts	(63)	220
496	Phenothiazine and its compounds	various	320
497	Phenprobamate	510	71
498	Phenprocoumon	511	273
499	<i>N</i> -Phenylacetylurea	489	269
500	4-Phenylazophenylene-1,3-diamine citrate hydrochloride	169	81
501	Phenylbutazone	117	67
502	4-Phenylbut-3-en-2-one	83	356
503	<i>N</i> -(2-Phenylbutyl)urea	298	272
504	<i>N</i> -[2-(α -Phenyl- <i>p</i> -chlorobenzyl)-ethyl]morpholine	230	270
505	1-Phenylcyclopentanecarboxylic acid diethylaminoethyl ester and its salts	127	169
506	2-Phenylcyclopropylamine (<i>trans</i> -form) and its salts	634, 635	324
507	1-Phenyl-2,3-dimethyl-4-isopropylpyrazol-5-one	547	138
507A	<i>o</i> -Phenylenediamine and its salts	208A	363
508	2-Phenylindan-1,3-dione	492	271
509	α -Phenyl-2-piperidineacetic acid methyl ester and its salts	422	175
510	1-Phenylpropan-1-ol carbamate	497	71
511	3-(α -Phenylpropyl)-4-hydroxy-coumarin	498	273
512	1-Phenyl-2-(2-pyridylamino)ethanol	303, 515	274
513	2-Phenylquinoline-4-carboxylic acid, its salts and derivatives and salts of those derivatives	171	8
514	6-Phenyl-2,4,7-triaminopteridine and its salts	637	275

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
515	Phenylamidol	303, 512	274
516	Phosphides, metal	—	279
517	Phosphorus	—	279
518	4-Phosphoryloxy- <i>N,N</i> -dimethyl-tryptamine	549	278
519	3-Phthalimidopiperidine-2,6-dione and its salts	616	280
520	Phthalylsulphathiazole and its salts	(592)	307
521	<i>Physostigma venenosum</i> Balf.	123	281
522	Physostigmine and its salts	282	166
522A	Picric acid	356A, 653A	268
523	Picrotoxin	176	282
524	Pilocarpine and its salts	—	283
525	<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	—	311
526	Pipazetate and its salts	527	118
527	2-(2-Piperidinoethoxy)ethyl-10-thia-1,9-diazaanthracene-9-carboxylate and its salts	526	118
528	α -Piperidin-2-ylbenzyl acetate, laevorotatory <i>threo</i> -form	381	284
529	β -(2-Piperidyl)propionaldehyde and its salts	475	263
530	Pipradrol and its salts	269	285
531	Piprocuarium iodide	220	137
532	Poldine metilsulfate (or methylsulphate)	76	239
533	Polyacetaldehyde	398	223
534	Potassium nitroferricyanide	14, 535	255
535	Potassium nitroprusside	14, 534	255
536	Probenecid	273	161
537	Procainamide, its salts and derivatives	29	25
538	Prochlorperazine and its salts	(496)	320
539	Progestogens (except progesterone and ethisterone)	—	194
540	Promazine and its salts	(496)	320
541	Promethazine and its salts	(496)	320
542	Propane-1,2,3-triyl trinitrate	322, 455	253
543	Propatylnitrate	98	206
544	1-Propyl-3-(4-chlorobenzene-sulphonyl)urea	161	79

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
545	2-Propylpiperidine	181	290
546	1-(2-Propynyl)cyclohexyl carbamate	340	115
547	Propyphenazone	507	138
548	<i>Prunus laurocerasus L.</i>	138	291
549	Psilocybine	518	278
550	<i>Pyrethrum album L.</i> and its galenical preparations	—	345
551	Pyrianisamine maleate	407	346
552	Pyribenzamine	86, 656	347
553	Quinalbarbitone and its salts	(63)	220
554	Radioactive substances (except substances which are radioactive naturally or by reason of contamination from the environment, which have not been enriched for manufacturing purposes, and of which the concentration complies with Council Directive No. 76/579/Euratom(a))	—	293
555	<i>Rauwolfia serpentina</i> alkaloids and their salts	556	15
556	Reserpine and its salts	(555)	15
557	α -Santonin	337	217
558	Safrole (except natural content of essences in cases where the concentration of such safrole in the cosmetic product does not exceed— (a) in the case of oral hygiene or dental products other than toothpaste intended specifically for children, 50 ppm; or (b) in the case of products other than oral hygiene or dental products, 100 ppm.)	—	360
559	<i>Schoenocaulon officinale Lind.</i> (seeds and galenical preparations)	—	332
560	Scopolamine, its salts and derivatives	358	295
561	Secbutobarbitone and its salts	(63)	220
562	Selenium and its compounds	—	297

(a) O.J. No. L187, 12.7.1976, p.1.

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
563	Sodium hexacyclonate	352	114
564	Sodium nitroferricyanide	14, 565	255
565	Sodium nitroprusside	14, 564	255
566	<i>Solanum nigrum L.</i> and its galenical preparations	—	298
567	Spanish Fly	124	69
568	Sparteine and its salts	386	299
569	Spirolactone	9	4
570	Squill and its preparations	660	330
571	Stramonium and its preparations	201	301
572	Strophantines and their aglucones and their respective derivatives	—	302
573	<i>Strophantus</i> species and their galenical preparations	—	303
574	Strychnine and its salts	—	304
575	<i>Strychnos</i> species and their galenical preparations	461	305
576	Succinonitrile	—	150
577	Succinylsulphathiazole and its salts	(592)	307
578	Sulfinpyrazone	268	155
579	Sulphacetamide and its salts	(592)	307
580	Sulphadiazine and its salts	(592)	307
581	Sulphadimethoxine and its salts	(592)	307
582	Sulphadimidine and its salts	(592)	307
583	Sulphafurazole and its salts	(592)	307
584	Sulphaguanidine and its salts	(592)	307
585	Sulphamethizole and its salts	(592)	307
586	Sulphamethoxazole and its salts	(592)	307
587	Sulphamethoxydiazine and its salts	(592)	307
588	Sulphamethoxyridazine and its salts	(592)	307
589	Sulphanilamide and its salts	(592)	307
590	Sulphapyridine and its salts	(592)	307
591	Sulphathiazole and its salts	(592)	307
592	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH ₂ groups) and their salts	various	307
593	Sulthiame	594, 612	308
594	Sultiame	593, 612	308

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
595	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe	41	21
596	Tefazoline and its salts	611	237
597	Tellurium and its compounds	—	312
598	TEPP	609	276
599	2-(4- <i>tert</i> -Butyl-2,6-dimethylbenzyl)-imidazoline and its salts	672	313
600	4- <i>tert</i> -Butylphenol	—	340
601	4- <i>tert</i> -Butylpyrocatechol	—	341
602	Tetrabenazine and its salts	469	139
603	Tetrabromosalicylanilides (except as those impurities of tribromosalicylanilide permitted in accordance with the requirements specified in column 4 of Part II of Schedule 2)	—	350
604	Tetracaine and its salts	244	63
605	Tetrachloroethylene	485	314
606	Tetrachloromethane	131	315
607	Tetrachlorosalicylanilides	—	348
608	Tetraethylammonium bromide	615	61
609	Tetraethyl pyrophosphate	598	276
610	5,6,6a,7-Tetrahydro-6-methyl-4 <i>H</i> -dibenzo[de, g]quinoline-10,11-dihydric alcohol and its salts	54	42
611	2-(5,6,7,8-Tetrahydro-1-methyl-2-naphthyl)-2-imidazoline and its salts	596	237
612	4-(Tetrahydro-2 <i>H</i> -1,2-thiazin-2-yl)-benzenesulphonamide <i>S,S</i> -dioxide	593, 594	308
613	<i>N</i> ,2,3,3-Tetramethyl-2-norcamphanamine	391	229
614	Tetramethylthiuram disulphide	274, 625	162
615	Tetrylammonium bromide	608	61
616	Thalidomide and its salts	519	280
617	Thallium and its compounds	—	317
618	<i>Thevetia nerifolia</i> Juss., glycoside extract	—	318
619	Thiamazole	421	233

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
620	2,2'-Thiobis(4,6-dichlorophenol)	100	352
621	Thiopentone and its salts	(63)	220
622	Thioridazine and its salts	(496)	320
623	Thiotepa	638, 648	310
624	Thiourea and its derivatives (except the one listed in part I of Schedule 2)	—	321
625	Thiram	274, 614	162
626	Thiuram disulphides	—	354
627	Thiuram monosulphides	—	353
628	Thyropropic acid and its salts	351	9
629	Tolboxane	632	177
630	Tolbutamide	119	65
631	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	37	32
632	<i>p</i> -Tolylboric acid ester of 2-methyl-2-propylpropane-1,3-diol	629	177
633	3-Tolyloxypropane-1,2-diol	393	322
634	<i>trans</i> -2-Phenylcyclopropylamine and its salts	506, 635	324
635	Tranlycypromine and its salts	506, 634	324
636	Tretamine	647	328
637	Triamterene and its salts	514	275
638	Triaziridin-1-ylphosphine sulphide	623, 648	310
639	2,2,2-Tribromoethanol	640	326
640	Tribromoethyl alcohol	639	326
641	Trichlormethine and its salts	645	327
642	Trichloroacetic acid	—	10
643	1,1,1-Trichloro-2,2-bis(4-chlorophenyl)ethane	174, 202	123
644	2,2,2-Trichloroethane-1,1-diol	139	77
645	Tri(β -chloroethyl)amine and its salts	641	327
645A	Trichloromethane	148A	—
646	Tricresyl phosphate	658	277
647	2,4,6-Triethyleneimino-1,3,5-triazine	636	328
648	<i>N,N,N</i> -Triethylenethiophosphamide	623, 638	310
649	Trifluoperazine and its salts	(496)	320
650	Trifluoperidol	306	188

Column 1	Column 2	Column 3	Column 4
Number in this Schedule	Name of substance	Cross-reference to this Schedule	Cross-reference to Annex II of the Directive
651	3,3',5-Triiodothyroacetic acid and its salts	350	5
652	3,4,5-Trimethoxyphenethylamine and its salts	396	222
653	2,2,6-Trimethyl-4-piperidyl benzoate and its salts	69	51
653A	2,4,6-Trinitrophenol	356A, 522A	268
654	Trioxysalan (except natural content of essences)	315, 316	358
655	Triparanol	221	92
656	Tripelennamine	86, 552	347
657	1,2,3-Tris(2-triethylammonium-ethoxy) benzene triiodide	319	329
658	Tritolyl phosphate	646	277
659	Tuaminoheptane, its isomers and salts	30	27
660	<i>Urginea scilla Stern.</i> and its galenical preparations	570	330
661	Vaccines, toxins and serums listed in the Annex to Council Directive No. 75/319/EEC(a)	—	323
662	Valnoctamide	297	184
663	Veratrine, its salts and galenical preparations	—	331
664	<i>Veratrum album L.</i> (roots and galenical preparations)	—	333
665	Vinyl chloride monomer	—	334
666	Vinylidene chloride	7, 215	126
667	Vitamins D ₂ and D ₃	166, 280	335
668	Warfarin and its salts	2, 354	203
669	Xanthates	15.	336
670	Xanthinol	349	135
671	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	38	33
672	Xylometazoline and its salts	599	313
673	Yohimbine and its salts	—	337
674	Zoxazolamine	28	24

(a) O.J. No. L147, 9.6.1975, p.13.

Regulations 6(3) and 8(1)

SCHEDULE 2

RESTRICTED SUBSTANCES

In this Schedule, the matters specified in columns 3, 4, 5 and 6 which apply to a particular substance are those set out to the right of its name as mentioned in column 2; and the matters specified in columns 4, 5 and 6 which apply in any particular case are those set out to the right of the matter specified in column 3 which applies in that case. The substance may not be used except for the purposes or contained other than in the types of product specified in column 3. The concentration of the substance in a product may not exceed the limit specified in column 4: where the names of two or more substances are mentioned in a single item as set out in column 2 and a product contains more than one of those substances, the limit specified in column 4 is the limit for all of those substances taken together; and where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 5. In column 4 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

PART I
Substances listed in Annex III, Part 1 of the Directive as Substances which cosmetic products must not contain except subject to the restrictions laid down.

Column 1 Reference Number	Column 2 Name of substance	Column 3 Purpose of substance or type of product	Column 4 Maximum concentration of substance in product	Column 5 Other requirements	Column 6 Required information
1	Boric acid	Talcum powder (see also Part II of Schedule 5) Oral hygiene products (See also Part II of Schedule 5) Other products (See also Part II of Schedule 5)	5 per cent. 0.5 per cent. 3 per cent.	Not to be used in products intended for children less than three years old	Not to be used for children under three years of age — —
2	Thioglycollic acid, its salts and esters	Hair waving or straightening products for general use Hair waving or straightening products for professional use Depilatories Other hair care products which are removed after application Hair care products	8 per cent. (Calculated as thioglycollic acid) ready for use 11 per cent. (Calculated as thioglycollic acid) ready for use 5 per cent. (Calculated as thioglycollic acid) 2 per cent. (Calculated as thioglycollic acid) 5 per cent.	pH value not to exceed 9.5 pH value not to exceed 9.5 pH value not to exceed 12.7 — —	Contains thioglycollic acid. Follow the instructions Contains thioglycollic acid. For professional use only Contains thioglycollic acid. Follow the instructions Contains thioglycollic acid. Follow the instructions For professional use only
3	Oxalic acid, its esters and alkaline salts				

PART I (Continued)

Substances listed in Annex III, Part I of the Directive as Substances which cosmetic products must not contain except subject to the restrictions laid down.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
4	Ammonia	All purposes and products	6 per cent. Calculated as NH ₃	—	Contains ammonia (not required when concentration is not more than 2 per cent.)
5	Tosylchloramide Sodium	All purposes and products	0.2 per cent.	—	—
6	Chlorates of alkali metals	Toothpaste Other uses	5 per cent. 3 per cent.	— —	— —
7	Dichloromethane	All purposes and products	35 per cent. (and when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 per cent.)	Purity of the dichloromethane must be not less than 99.8 per cent.	—
8	<i>m</i> - and <i>p</i> -Phenylenediamines, their <i>N</i> -substituted derivatives and their salts; <i>N</i> -substituted derivatives of <i>o</i> -phenylenediamines	Oxidizing colouring agents for hair dyeing for general use	6 per cent. Calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Can cause an allergic reaction. Sensitivity test advisable before use. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows
		Oxidizing colouring agents for hair dyeing for professional use	6 per cent. Calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	For professional use only Contains phenylenediamines. Can cause an allergic reaction. Sensitivity test advisable before use

9	Methylphenylenediamines (other than 4-methyl- <i>n</i> -phenylenediamine and its salts), their <i>N</i> -substituted derivatives and their salts	Oxidizing colouring agents for hair dyeing for general use	10 per cent., calculated as a free base, subject to the provisions of "Combination Rule A" set out below	Can cause an allergic reaction. Sensitivity test advisable before use. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows
10	Diaminophenols	Oxidizing colouring agents for hair dyeing for professional use	10 per cent., calculated as a free base, subject to the provisions of "Combination Rule A" set out below	For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Sensitivity test advisable before use
11	Dichlorophen	Oxidizing colouring agents for hair dyeing for professional use	10 per cent., calculated as a free base, subject to the provisions of "Combination Rule A" set out below	Can cause an allergic reaction. Sensitivity test advisable before use. Contains diaminophenols. Do not use to dye eyelashes or eyebrows
12	Hydrogen peroxide	Use other than as a preservative (See also Part II of Schedule 5) Hair care products	0.5 per cent.	For professional use only. Contains diaminophenols. Can cause allergic reaction. Sensitivity test advisable before use
13	Formaldehyde	Nail hardeners (See also Part I of Schedule 5)	12 per cent. 5 per cent.	Contains dichlorophen Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them Protect cuticles with grease or oil. Contains formaldehyde (Not required when concentration is not more than 0.05 per cent.)

PART I (Continued)
Substances listed in Annex III, Part 1 of the Directive as Substances which cosmetic products must not contain except subject to the restrictions laid down.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
14	Hydroquinone	Oxidizing colouring agent for hair dyeing for general use (See also Part III of this Schedule)	2 per cent. subject to the provisions of "Combination Rule B" set out below	—	Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains hydroquinone.
15	Potassium and sodium hydroxides	Oxidizing colouring agent for hair dyeing for professional use (See also Part III of this Schedule) Nail cuticle solvent Hair straightener for general use Hair straightener for professional use pH adjuster for depilatories Other uses as pH adjuster	2 per cent. subject to the provisions of "Combination Rule B" set out below 5 per cent. calculated as sodium hydroxide 2 per cent. calculated as sodium hydroxide 4.5 per cent. calculated as sodium hydroxide	— — — pH values not to exceed 12.7 pH value not to exceed 11	For professional use only. Contains hydroquinone Rinse eyes immediately if product comes into contact with them Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children For professional use only. Avoid contact with eyes. Can cause blindness Keep out of reach of children. Avoid contact with eyes —

16	α -Naphthol	Colouring agent for hair dyeing	0.5 per cent.	—	Contains α -naphthol
17	Sodium nitrite	Rust inhibitor	0.2 per cent.	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	—
18	Nitromethane	Rust inhibitor	0.3 per cent.	—	—
19	Phenol and its alkali salts	Soaps and shampoos	1 per cent. calculated as phenol	—	Contains phenol
20	Pyrogallol	Oxidizing colouring agent for hair dyeing for general use	5 per cent., subject to the provisions of "Combination Rule set out below"	—	Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains pyrogallol
		Oxidizing colouring agent for hair dyeing for professional use	5 per cent., subject to the provisions of "Combination Rule set out below"	—	For professional use only. Contains pyrogallol. Rinse eyes immediately if product comes into contact with them
21	Quinine and its salts	Shampoos	0.5 per cent. calculated as quinine base	—	—
		Hair lotions	0.2 per cent. calculated as quinine base	—	—

PART I (Continued)

Substances listed in Annex III, Part 1 of the Directive as Substances which cosmetic products must not contain except subject to the restrictions laid down.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
22	Resorcinol	Oxidizing colouring agent for hair dyeing for general use	5 per cent. subject to the provisions of "Combination Rule B"; set out below	—	Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them
		Oxidizing colouring agent for hair dyeing for professional use	5 per cent. subject to the provisions of "Combination Rule B"; set out below	—	For professional use only. Contains resorcinol. Rinse eyes immediately if product comes into contact with them
		Hair lotions and shampoos	0.5 per cent., subject to the provisions of "Combination Rule B"; set out below	—	Contains resorcinol
23	Alkali sulphides	Depilatories	2 per cent. calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes
24	Alkaline earth sulphides	Depilatories	5 per cent. calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes
25	Water-soluble zinc salts with the exception of zinc 4-hydroxybenzenesulphonate	All purposes and products	1 per cent. calculated as zinc	—	—
26	Zinc 4-hydroxybenzenesulphonate	Deodorants, antiperspirants and astringent lotions	6 per cent. calculated as percentage of anhydrous substance	—	Avoid contact with eyes

27	Ammonium monofluorophosphate	Oral hygiene products	0.15 per cent. calculated as fluorine. When mixed with other fluorine compounds total fluorine concentration must not exceed 0.15 per cent.	Contains ammonium monofluorophosphate
28	Sodium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	Contains sodium monofluorophosphate
29	Potassium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	Contains potassium monofluorophosphate
30	Calcium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	Contains calcium monofluorophosphate
31	Calcium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains calcium fluoride
32	Sodium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains sodium fluoride
33	Potassium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains potassium fluoride
34	Ammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains ammonium fluoride
35	Aluminium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains aluminium fluoride
36	Stannous fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains stannous fluoride
37	Hexadecyl ammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains hexadecyl ammonium fluoride
38	3-(<i>N</i> -Hexadecyl- <i>N</i> -2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride	Oral hygiene products	As for ammonium monofluorophosphate	Contains 3-(<i>N</i> -hexadecyl- <i>N</i> -2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride

PART I (Continued)

Substances listed in Annex III, Part 1 of the Directive as Substances which cosmetic products must not contain except subject to the restrictions laid down.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
39	<i>N,N'</i> -Tris(polyoxyethylene)- <i>N</i> -hexadecylpropylenediamine dihydrofluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains <i>NN'</i> -tris(polyoxyethylene)- <i>N</i> -hexadecylpropylenediamine dihydrofluoride
40	Octadecenyl ammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains octadecenyl ammonium fluoride
41	Sodium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium fluorosilicate
42	Potassium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains potassium fluoro-silicate
43	Ammonium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains ammonium fluoro-silicate
44	Magnesium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains magnesium fluoro-silicate
45	1,3-Bis(hydroxymethyl)imidazolidene-2-thione	Hair care preparations	2 per cent.	Not to be used in aerosol dispensers	Contains 1,3-Bis(hydroxymethyl)imidazolidene-2-thione

46	Benzyl alcohol (See also Part II of Schedule 5)	Solvents, perfumes and flavourings	—	—	—
47	6-Methylcoumarin	Oral hygiene products	0.003 per cent.	—	—

Combination Rules

- A. Where a cosmetic product contains two or more substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 1.
- B. Where a cosmetic product contains the substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 2; but the concentration of each substance shall not in any event exceed the limit specified for the substance in respect of the product in column 4 above.
- C. The relevant quotient for each substance is the actual concentration of the substance in the product divided by the maximum concentration specified for the substance in respect of the product in Column 4 of this Schedule.

PART II
Substances listed in Annex IV, Part 1 of the Directive as substances provisionally allowed

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
1	Methanol	Denaturant for ethanol and isopropyl alcohol	5 per cent. of the ethanol and isopropyl alcohol	—	—
2	2,3-Dihydroxypropyl-4-amino-benzoate	All purposes and products	5 per cent.	—	Contains 2,3-dihydroxypropyl-4-aminobenzoate
3	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	Stabiliser for peroxides (See also Part II of Schedule 5)	0.3 per cent. as base	Not to be used in products intended for application after sunbathing. Not to be used in talcum powder intended for children less than three years old	Not to be used for children less than three years old
4	1,1,1-Trichloroethane (methyl chloroform)	Solvent for aerosol dispensers	35 per cent. (and when mixed with dichloromethane total concentration must not exceed 35 per cent.)	—	Do not spray on a naked flame or any incandescent material
5	3,4',5-Tribromosalicylanilide (Tribromsalan)	Soaps	1 per cent.	Purity of the 3,4',5-Tri-bromosalicylanilide: must be not less than 98.5 per cent. Other bromosalicylanilides not to exceed 1.5 per cent. 1',5-Dibromosalicylanilide not to exceed 0.1 per cent. Inorganic bromide not to exceed 0.1 per cent. expressed as NaBr	Contains tribromosalicylanilide

6	Silver nitrate	Products to dye eyelashes or eye brows	4 per cent.	—	Contains silver nitrate. Rinse eyes immediately if product comes into contact with them
7	Aluminium zirconium chloride hydroxide complexes $Al_3Zr(OH)_3Cl_3$ and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	20 per cent. as anhydrous aluminium zirconium chloride hydroxide 5.4 per cent. as zirconium	The ratio of the number of aluminium atoms to zirconium atoms must be between 2 and 10. The ratio of the number of (Al+Zr) atoms to chlorine atoms must be between 0.9 and 2.1. Not to be used in aerosol dispensers	—

PART III
Substances excluded from the scope of the Directive (mentioned in Annex V)

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
1	Hydroquinone	Skin lightener	2 per cent.	—	Avoid contact with the eyes. Do not use on children under twelve years old. Apply only to small areas. If irritation develops discontinue use. Contains hydroquinone
2	Lead acetate	Hair care products	3 per cent.	—	Wash hands after use. Do not use on broken or abraded skin. Keep out of reach of children. Contains lead acetate
3	Oestrone	All purposes and products	0.004 per cent.	—	—
4	Thiomersal and phenylmercuric compounds	To preserve concentrated shampoos and hair creams which contain non-ionic emulsifiers which render other preservatives ineffective (See also Part II of Schedule 5)	0.003 per cent. calculated as mercury. When mixed with other mercury compounds the total mercury concentration must not exceed 0.007 per cent.	—	—

SCHEDULE 3

COLOURING AGENTS

In this Schedule, the colouring agents referred to in Regulation 6(4)(a) are—

- (i) those identified in column 1 either by name or by colour index number (the colour index numbers being those specified in the third edition of *The Colour Index* published in 1971 by the Society of Dyers and Colourists);
- (ii) the lakes and salts of those of the said agents which do not include any barium, zirconium or strontium salts and lakes other than those identified by the letter “B” in column 1 of the Schedule.

In column 2 of this Schedule—

“E” followed by a number means that the requirements as to purity which are set out in the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption (a), as amended(b) and adapted(c), and which relate to the colouring agent designated by that number in that Directive must be complied with. These requirements do not apply to lakes, salts or pigments of barium, strontium or zirconium;

“MC” followed by a percentage (expressed by mass, m/m) indicates the maximum permitted concentration of the agent in the cosmetic product in which it is contained. In the case of agents CI 12085 and 15630, any concentration of the metal compounds referred to in paragraph (ii) above in the cosmetic product shall not be included in the calculation of the level of concentration.

“R” indicates that the agent may not be contained in eye make-up, eye make-up remover or other cosmetic products which in the normal course of use may come into contact with the mucous membranes of the eye.

(a) O.J. No. 115, 11.11.1962, p. 2645.

(b) Council Directives Nos. 65/469/EEC, 67/653/EEC, 68/419/EEC, 70/758/EEC, 76/399/EEC and 78/144/EEC (O.J. Nos. L178, 26.10.1965, p. 2793; 263, 30.10.1967, p. 4; L309, 24.12.1968, p. 24; L157, 18.7.1970, p. 36; L108, 26.4.1976, p. 19; L44, 15.2.1978, p. 20).

(c) Annexes I and VII to the Act of Accession of 22 January 1972, as adjusted by the Council Decision of 1 January 1973 (O.J. No. L2, 1.1.1973, p. 1).

PART I

Colouring agents listed in Annex III, part 2 of the Directive as colouring agents which can be contained in cosmetic products intended to come into contact with the mucous membranes.

Column 1	Column 2
Name or colour index number	Requirements
Group (a): Reds	
12085 B	MC 3 per cent.
12150	—
12490	—
14720	E 122
14815	—
15525	—
15580	—
15585 B	R
15630 B	MC 3 per cent.
15850 B	—
15850(A1)	E 180
15850:1	E 180
15865 B	—
15880	—
16185	E 123
16255 B	E 124
16290	—
45170 B	—
45170:1	R
45370 B	Not more than 1 per cent. 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid and 2 per cent. 2-(bromo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid
45380 B	As for 45370
45405	R Acid concentration limited as for 45370
45410 B	As for 45370
45425	Not more than 1 per cent. 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid and 3 per cent. 2-(iodo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid
45430 B	E 127 Acid concentration limited as for 45425
58000	—
73360	—
75470	E 120

Column 1	Column 2
Name or colour index number	Requirements
Group (a): Reds (<i>Continued</i>)	
77015	—
77491	E 172
Colouring agent numbered E 163 in Council Directive of 23 October 1962	E 163
Colouring agent numbered E 162 in Council Directive of 23 October 1962	E 162
Group (b): Oranges and yellows	
10316 B	R
11920	—
12075 B	—
13015	—
14270	—
15510 B	R
15980	—
15985 B	E 110
19140 B	E 102
45350	MC 6 per cent.
47005	E 104
75100	—
75120	E 160b
75125	E 160d
75130	E 160a
75135	E 161d
75300	E 100
77489	E 172
77492	E 172
40820	E 160e
40825	E 160f
Colouring agent numbered E 101 in Council Directive of 23 October 1962	E 101
45396	In lipstick the colouring agent must be in free acid form and of a concentration not exceeding 1 per cent.
Colouring agent numbered E160c in Council Directive of 23 October 1962	E 160c
Group (c): Greens and blues	
42051 B	E 131
42053	—

Column 1	Column 2
Name or colour index number	Requirements
<i>Group (c): Greens and blues (Continued)</i>	
42090	—
44090	E 142
61565	—
61570	—
69825	—
73000	—
73015	E 132
74260	R
75810	E 140
Colouring agent numbered E 141 in Council Directive of 23 October 1962	E 141
77007	—
77346	—
77510	The product must be free from cyanide ions (except for any trace which cannot reasonably be removed during or after manufacture)
69800	—
<i>Group (d): Violets, browns, blacks and whites</i>	
28440	E 151
42640	—
60725	—
73385	—
77000	E 173
77002	—
77004	—
77120	—
77220	E 170
77231	—
77266	—
77267	—
77268:1	E 153
77400	—
77480	E 175
77499	E 172
77713	—
77742	—

Column 1	Column 2
Name or colour index number	Requirements
Group (d): Violets, browns, blacks and whites (<i>Continued</i>)	
77745	—
77820	E 174
77891 (titanium dioxide and its mixtures with mica)	—
77947	—
75170 (guanine or pearl essence)	—
(White 9) Aluminium, zinc, magnesium and calcium stearates	—
Caramel	E 150

Part II

Colouring agents listed in Annex IV, part 2 of the Directive as colouring agents provisionally allowed which may be contained in cosmetic products intended to come into contact with the mucous membranes in accordance with article 5.

Column 1	Column 2
Name or colour index number	Requirements
Group (a): Reds	
12120	—
14700	R
15620	—
15800	—
16035	—
17200	—
26100	—
27290 B	—
45160	—
75480	—
Group (b): Oranges and yellows	
18965	—
40850	E 161g
47000	R

Column 1	Column 2
Name or colour index number	Requirements
Group (c): Greens and blues	
42040	—
42140	—
42170	—
42735	—
44040	—
44045	—
59040	—
61554	—
62085	—
77288	The product must be free from chromate ions (except for any trace which cannot reasonably be removed during or after manufacture)
77289	As for 77288
77520	—
74160	—
Group (d): Violets, browns, blacks and whites	
20170	—
27755	—
42580	—
45190	—
77019	—
77163	—
(bismuth chloride oxide and its mixtures with mica)	
77265	—

Regulation 6(5)

SCHEDULE 4

Colouring agents listed in Annex IV, part 3(B) of the Directive as colouring agents provisionally allowed for cosmetic products which come into contact only briefly with the skin.

In this Schedule, the colouring agents referred to in Regulation 6(5) are identified by colour index number or name, as specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists.

Reds

11 210, 12 370, 12 459, 12 467, 12 475, 12 485, 12 512, 12 513, 12 715, 14 895, 14 905, 16 045, 18 125, 18 130, 23 266, 24 790, 27 300, 27 306, 28 160, 45 110, 45 150, 45 220, 60 710, 62 015, 69 025, 71 100, 73 312, 73 905, 73 915, Pigment Red 144, Pigment Red 166.

Yellows and oranges

11 725, 11 727, 11 730, 11 765, 11 767, 11 855, 11 870, 12 055, 12 140, 12 700, 12 790, 14 600, 14 690, 15 970, 18 820, 19 005, 20 040, 21 096, 21 100, 21 105, 21 108, 21 110, 21 115, 22 910, 23 900, 25 135, 25 220, 26 090, 29 020, 40 215, 48 040, 48 045, 48 055, 56 205, 75 660, 77 199, 77 878, 77 955, Pigment Yellow 93, Pigment Orange 31.

Blues and greens

12 775, 34 230, 42 052, 42 085, 42 095, 42 100, 42 563, 50 315, 50 405, 52 015, 52 020, 61 135, 61 505, 61 525, 61 585, 62 005, 62 045, 62 105, 62 560, 69 810, 74 180, 74 255, Solvent Blue 19, Acid Blue 82, Acid Blue 181, Acid Blue 272.

Violets, browns, blacks and whites

14 805, 17 580, 20 285, 20 470, 21 010, 25 410, 42 510, 42 520, 42 535, 42 650, 45 175, 50 325, 60 010, 60 724, 60 730, 61 105, 62 030, Acid Brown 19, Acid Brown 82, Acid Brown 104, Acid Brown 106, Pigment Violet 37, Pigment Brown 30.

Regulations 6(6) and 8(1)

SCHEDULE 5

PRESERVATIVES

In this Schedule, the matters specified in columns 3, 4, 5 and 6 which apply to a particular substance are those set out to the right of its name as mentioned in column 2; and the matters specified in columns 4, 5 and 6 which apply in any particular case are those set out to the right of the matter specified in column 3 which applies in that case. The substance may not be contained other than in the types of product specified in column 3. The concentration of the substance, when it is used as a preservative, in a product may not exceed the limit set out in column 4. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 5.

In column 4 of this Schedule, "A" indicates that the concentration of the substance in a product may exceed the limit set out in that column provided that:—

- (a) the presence of any excess of the substance in a product over the concentration so set out is not for the primary purpose of inhibiting the development of micro-organisms; and
- (b) the purpose for which any such excess is present in the product is apparent from the labelling of the product.

In this Schedule—

"salts" means salts of the cations sodium, potassium calcium, magnesium, ammonium and ethanolamines and of the anions chloride, bromide, sulphate and acetate;

"esters" means esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

In column 4 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

PART I
Preservatives listed in Annex VI, Part 1 of the Directive as preservatives allowed.

Column 1 Reference Number	Column 2 Name of substance	Column 3 Purpose of substance or type of product	Column 4 Maximum concentration of substance in product	Column 5 Other requirements	Column 6 Required information
1	Benzoic acid, its salts and esters	All products	0.5 per cent. (acid)	—	—
2	Propionic acid and its salts	All products	2 per cent. (acid)	—	—
3	Salicylic acid and its salts	All products	0.5 per cent. (acid)	Not to be used in products, other than shampoos, intended for children less than three years old	Not to be used for children under three years old. (Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	All products	0.6 per cent. (acid) When mixed with sorbic acid esters, the total concentration of the acids, salts and esters must not exceed 0.6 per cent. (acid)	—	—
5	Formaldehyde and paraformaldehyde	Oral hygiene products	0.1 per cent. (expressed as free formaldehyde)	For products other than foams, not to be used in aerosol dispensers	Contains formaldehyde [Not required when concentration is not more than 0.05 per cent.]
		Other products (See also Part I of Schedule 2)	0.2 per cent. (expressed as free formaldehyde)	For products other than foams, not to be used in aerosol dispensers	Contains formaldehyde [Not required when concentration is not more than 0.05 per cent.]
6	Hexachlorophene (INN)	All products	0.1 per cent.	Not to be used in products for children less than three years old or in personal hygiene products	Not to be used for children under three years of age. Contains hexachlorophene
7	Biphenyl-2-ol (o-phenylphenol) and its salts	All products	0.2 per cent. expressed as the phenol	—	—

PART I

Preservatives listed in Annex VI, Part I of the Directive as preservatives allowed.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Purpose of substance or type of product	Maximum concentration of substance in product	Other requirements	Required information
8	Pyrrithione zinc (INN)	Products rinsed off after use	0.5 per cent.	Not to be used in oral hygiene products	—
9	Inorganic sulphites and hydrogensulphites	All products	0.2 per cent. expressed as SO ₂	—	—
10	Sodium iodate	Products rinsed off after use	0.1 per cent.	—	—
11	Chlorobutanol (INN)	All products	0.5 per cent.	For products other than foams, not to be used in aerosol dispensers	Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters except benzyl ester	All products	0.4 per cent. (acid) for I ester, 0.8 per cent. (acid) for mixtures of esters	—	—

PART II
Preservatives listed in Annex VI, Part 2 of the Directive as preservatives provisionally allowed.

Column 1 Reference Number	Column 2 Name of substance	Column 3 Type of product	Column 4 Maximum concentration of substance in product	Column 5 Other requirements	Column 6 Required information
1	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	All products	0.2 per cent.	—	—
2	Boric acid	Oral hygiene products (See also Part I of Schedule 2)	0.5 per cent. A	—	—
3	Chlorphenesin (INN)	Other products (See also Part I of Schedule 2)	3 per cent. A	—	—
4	3-Acetyl-6-methylpyran-2,4(3H)-dione (Dehydracetic acid) and its salts	All products	0.5 per cent. A	—	—
5	Formic acid	All products	0.6 per cent. (acid)	—	—
6	4-Hydroxybenzoic acid benzyl ester	All products	0.5 per cent. (acid) A	—	—
7	Hexamidine (INN) and its salts (including isethionate (INN) and 4-hydroxybenzoate)	All products	0.1 per cent. (acid)	—	—
8	3,3'-Dibromo-4,4'-hexamethylenedioxybenzamide (Dibromohexamidine) and its salts (including isethionate)	All products	0.1 per cent. A	—	—
9	Dibromopropamide (INN) and its salts including isethionate (INN)	All products	0.1 per cent.	—	—
10	Thiomersal (INN)	Eye make-up and eye make-up remover. (See also Part III of Schedule 2)	0.007 per cent. calculated as mercury. When mixed with other mercury compounds, total mercury concentration must not exceed 0.007 per cent.	—	Contains thiomersal

PART II (Continued)
Preservatives listed in Annex VI, Part 2 of the Directive as preservatives provisionally allowed.

Column 1 Reference Number	Column 2 Name of substance	Column 3 Type of product	Column 4 Maximum concentration of substance in product	Column 5 Other requirements	Column 6 Required information
11	Phenylmercuric salts (including borate)	Eye make-up and eye make-up remover	0.007 per cent. calculated as mercury, when mixed with other mercury compounds, total mercury concentration must not exceed 0.007 per cent.	—	Containing phenylmercuric compounds
12	Esters of sorbic acid (Hexa-2,4-dienoic acid)	All products	0.6 per cent. (acid) when mixed with sorbic acid and/or its salts, total concentration of acids, salts and esters must not exceed 0.6 per cent. (acid)	—	—
13	Undec-10-enoic acids; salts, esters, the amide, the mono- and bis(2-hydroxyethyl) amides and their sulphosuccinates	All products	0.2 per cent. (acid)	—	—
14	2,6-Diacetyl-1,2,3,9b-tetrahydro-7,9-dihydroxy-8,9b-dimethylidbenzofuran-1,3-dione (usnic acid) and its salts (including the copper salt)	All products	0.2 per cent.	—	—
15	Hexetidine (INN)	All products	0.2 per cent.	—	—
16	Benzylformal (a 1:1 mixture of benzyloxymethanol and (benzyloxymethoxy) methanol)	All products	0.2 per cent.	—	—
17	Clorofene (INN)	All products	0.2 per cent.	—	—
18	5-Bromo-5-nitro-1,3-dioxane	Products rinsed off after use	0.1 per cent.	—	—
19	Bronopol (INN)	All products	0.1 per cent.	—	—

20	6,6-Dibromo-4,4-dichloro-2,2-methylene-diphenol (Bromochlorophen)	All products	0.1 per cent.	A	—	—
21	Tetrabromo- <i>o</i> -cresol	All products	0.3 per cent.	A	—	—
22	2-Chloroacetamide	All products	0.3 per cent.	A	—	Contains chloroacetamide
23	3,4-Dichlorobenzyl alcohol	All products	0.15 per cent.	A	—	—
24	2,4-Dichlorobenzyl alcohol	All products	0.15 per cent.	A	—	—
25	Triclocarban (INN)	All products	0.2 per cent.	A	—	—
26	4-Chloro- <i>m</i> -cresol	All products	0.2 per cent.	A	—	—
27	Halocarban (INN)	Aerosols Other products	0.2 per cent. 0.3 per cent.	A A	— —	— —
28	Triclosan (INN)	All products	0.3 per cent.	A	—	—
29	Dichlorophen (INN)	All products (See also Part I of Schedule 2)	0.2 per cent.	A	—	Contains dichlorophen
30	N-(Trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (Captan (ISO))	All products	0.5 per cent.	A	—	—
31	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	All products	0.3 per cent.	A	—	—
32	4-Chloro-3,5-xyleneol	All products	0.5 per cent.	A	—	—
33	2,4-Dichloro-3,5-xyleneol	All products	0.1 per cent.	A	—	—
34	Quinolin-8-ol and its salts	All products (See also Part II of Schedule 2)	0.3 per cent.	A	—	Not to be used in products intended to be applied after sunbathing, or in talcum powders intended for children less than three years old

PART II (Continued)
Preservatives listed in Annex VI, Part 2 of the Directive as preservatives provisionally allowed.

Column 1 Reference Number	Column 2 Name of substance	Column 3 Type of product	Column 4 Maximum concentration of substance in product	Column 5 Other requirements	Column 6 Required information
35	1,3,5-Tris (2-hydroxyethyl)hexahydro-1,3,5-triazine	All products	0.3 per cent.	—	Contains 1,3,5-Tris (2-hydroxyethyl)hexahydro-1,3,5-triazine
36	3,3'-Bis (1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methyleneurea ("imidazolidinyl urea")	All products	0.6 per cent.	A	—
37	4-Isopropyl- <i>m</i> -cresol	All products	0.1 per cent.	—	—
38	2-Chloro- <i>N</i> -(hydroxymethyl)acetamide	Products rinsed off after use	0.3 per cent. for the chloracetamide	—	—
39	1-Hydroxymethyl-5,5-dimethylhydantoin	Products rinsed off after use	0.2 per cent. expressed as free formaldehyde	A	Contains formaldehyde [Not required when concentration is not more than 0.05 per cent.]
40	Pyrrithione sodium (INN)M	All products	0.5 per cent.	A	—
41	2,2'-Dithiobis(pyridine 1-oxide), addition product with magnesium sulphate trihydrate	All products	0.5 per cent.	A	—
42	Poly(1-hexamethyleneguanide hydrochloride)	All products	0.3 per cent.	A	—
43	2-Phenoxyethanol	All products	1 per cent.	A	—
44	Hexamethylenetetramine (methenamine) (INN)	All products	0.2 per cent. expressed as free formaldehyde	A	Contains formaldehyde [Not required when concentration is not more than 0.05 per cent.]
45	Mixture of 5-Chloro-2-methyl-isothiazol-3(2 <i>H</i>)-one and 2-methylisothiazol-3(2 <i>H</i>)-one with magnesium chloride and magnesium nitrate	All products	0.005 per cent. (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2 <i>H</i>)-one and 2-methylisothiazol-3(2 <i>H</i>)-one)	—	—

46	Pyridin-2-ol 1-oxide	Products rinsed off after use	0.5 per cent.	A	—	—
47	Pyrithione aluminium camsilate (INN ^M)	All products	0.2 per cent.		—	—
48	Methanamine 3-chloroallylochloride (INN ^M)	All products	0.2 per cent.		—	—
49	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one	All products	0.5 per cent.	A	—	—
50	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	All products	0.2 per cent. expressed as free formaldehyde	A	—	Contains formaldehyde [Not required when concentration is not more than 0.05 per cent.]
51	Benzyl alcohol	All products (See also Part I of Schedule 2)	1 per cent.	A	—	—
52	1-Dodecylguanidinium acetate (Dodine—ISO)	Products rinsed off after use	0.5 per cent.	A	—	—
		Other products	0.1 per cent.	A	—	—
53	Benzethonium chloride (INN)	All products	0.1 per cent.	A	—	—
54	Benzalkonium chloride (INN), (1,2-Benzisothiazol-3-(2H)-one 1,1-dioxide)	All products	0.5 per cent.	A	—	—
55	Benzalkonium bromide and saccharinate	All products	0.5 per cent.		—	—
56	Alkyl (C12-C22) trimethylammonium bromide and chloride (including Cetrimonium bromide (INN))	All products	0.1 per cent.	A	—	—

PART II (Continued)

Preservatives listed in Annex VI, Part 2 of the Directive as preservatives provisionally allowed.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	Name of substance	Type of product	Maximum concentration of substance in product	Other requirements	Required information
57	1-Phenoxypropan-2-ol	All products	1 per cent.	—	—
58	1-Hydroxy-4-methyl-(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt	Products rinsed off after use	1.0 per cent.	—	—
59	3-Heptyl-2-(3-heptyl-4-methyl-4-thiazolin-2-ylidenemethyl)-4-methylthiazolinium iodide	Other products Creams, toilet lotions and shampoos	0.5 per cent. 0.002 per cent.	—	—
60	1,2-Dibromo-2,4-dicyanobutane	All products	0.1 per cent.	Not to be used in sunscreen products	—
61	4,4-Dimethyl-1,3-oxazolidine	Products rinsed off after use	0.1 per cent.	pH value not to be lower than 6	—

*Regulations 6(7) and 8(1)***SCHEDULE 6****UV FILTERS**

In this Schedule, the matters specified in columns 3, 4 and 5 which apply to a particular substance are those set out to the right of its name as mentioned in column 2. The concentration of the substance in a product may not exceed the limit specified in column 3. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 4. In column 3 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

PART I
UV filters listed in Annex VII, Part 1, of the Directive as UV filters which cosmetic products may contain

Column 1	Column 2	Column 3	Column 4	Column 5
Reference Number	Name of substance	Maximum concentration of substance in product	Other requirements	Required information
1	4-Aminobenzoic acid	5 per cent.	—	
2	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulphate	6 per cent.	—	
3	Homosalate (INN)	10 per cent.	—	
4	Oxybenzone (INN)	10 per cent.	—	Contains oxybenzone. (Not required when concentration is not more than 0.5 per cent., and when the substance is only intended to protect the product.)
5	3-Imidazol-4-ylacrylic acid and its ethyl ester	2 per cent. (expressed as acid)	—	
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 per cent. (expressed as acid)	—	

PART II
 UV filters listed in Annex VII, Part 2 of the Directive as UV filters which cosmetic products may provisionally contain

Column 1	Column 2	Column 3	Column 4	Column 5
Reference Number	Name of substance	Maximum concentration of substance in product	Other requirements	Required information
1	Ethyl-4- <i>bis</i> (hydroxypropyl)aminobenzoate, mixed isomers	5 per cent.	—	—
2	Ethoxylated 4-aminobenzoic acid	10 per cent.	—	—
3	Padimate (INN)	5 per cent.	—	Contains padimate. (Not required when concentration is not more than 0.5 per cent. and when the substance is only intended to protect the product)
4	Glycerol 1-(4-aminobenzoate)	5 per cent.	Must not contain any benzocaine (INN)	—
5	2-Ethylhexyl-4-dimethylaminobenzoate	8 per cent.	—	—
6	2-Ethylhexylsalicylate	5 per cent.	—	—
7	3,3,5-Trimethylcyclohexyl-2-acetamidobenzoate	2 per cent.	—	—
8	Potassium cinnamate	2 per cent.	—	—
9	4-Methoxycinnamic acid salts (potassium, sodium and diethanolamine salts)	8 per cent. (expressed as acid)	—	—

PART II (Continued)

UV filters listed in Annex VII, Part 2 of the Directive as UV filters which cosmetic products may provisionally contain

Column 1	Column 2	Column 3	Column 4	Column 5
Reference Number	Name of substance	Maximum concentration of substance in product	Other requirements	Required information
10	Propyl-4-methoxycinnamate	3 per cent.	—	—
11	Salicylic acid salts (potassium, sodium and triethanolamine salts)	2 per cent. (expressed as acid)	The pH value of the finished product must be such that the acid is not liberated.	Not to be used for children under three years of age.
12	Amyl 4-methoxycinnamate mixed isomers	10 per cent.	—	—
13	2-Ethylhexyl 4-methoxycinnamate	10 per cent.	—	—
14	Cinoxate (INN)	5 per cent.	—	—
15	3,4-Dihydroxy-5-(3,4,5-trihydroxybenzoyloxy) benzoic acid, trioleate	4 per cent.	—	—
16	Mexenone (INN)	4 per cent.	—	Contains Mexenone (Not required when concentration is not more than 0.5 per cent. and when the substance is only intended to protect the product)

17	Sulisobenzone (INN) and sulisobenzone sodium (INN _M)	5 per cent. (expressed as acid)	—
18	2-Ethylhexyl-2-(4-phenylbenzoyl) benzoate	10 per cent.	—
19	5-Methyl-2-phenylbenzoxazole	4 per cent.	—
20	Sodium, 3,4-dimethoxyphenylglyoxylate	5 per cent.	—
21	1,3-bis(4-methoxyphenyl) propane-1,3-dione	6 per cent.	—
22	5-(3,3-Dimethyl-8,9,10-trinorborn-2-ylidene) pent-3-en-2-one	3 per cent.	—
23	α -(2-Oxoborn-3-ylidene)- <i>p</i> -xylene-2-sulphonic acid	6 per cent.	—
24	α -(2-Oxoborn-3-ylidene) toluene-4-sulphonic and its salts	6 per cent. (expressed as acid)	—
25	3-(4-Methylbenzylidene) bornan-2-one	6 per cent.	—
26	3-Benzylidenebornan-2-one	6 per cent.	—
27	α -Cyano-4-methoxycinnamic acid and its hexyl ester	5 per cent.	—
28	1- <i>p</i> -Cumenyl-3-phenylpropane-1,3-dione	5 per cent.	—
29	4-Isopropylbenzyl salicylate	4 per cent.	—
30	Cyclohexyl 4-methoxycinnamate	1 per cent.	—
31	1-(4- <i>tert</i> -Butylphenyl)-3-(4-methoxyphenyl) propane 1,3-dione	5 per cent.	—

Regulation 11

SCHEDULE 7

SAMPLING AND TESTING

1. In this Schedule—

“Annex A” means the Annex to Commission Directive No 80/1335/EEC(a);

“Annex B” means the Annex to Commission Directive No 82/434/EEC(b);

“Annex C” means the Annex to Commission Directive No 83/514/EEC(c);

“purchase” means purchase for the purpose of carrying out a test.

2. An enforcement authority intending to purchase a cosmetic product shall purchase a sufficient laboratory sample, as defined in paragraph 2.3 of Part I of Annex A, for the purposes of Annex A; and, for the purposes of the definition of “total sample” in paragraph 2.2 of Part I of Annex A, samples shall be regarded as having the same batch number if:

- (a) the means of identifying the batch referred to in Regulation 8(1)(g) above shows that they were manufactured in the same batch; or
- (b) in the case of a product not manufactured in a batch, the reference referred to in Regulation 8(1)(g) above shows that they are derived from the same unit of production; or
- (c) in the case of a product which does not comply with the requirements of Regulation 8(1)(g) above, the officer effecting the purchase has reasonable cause to believe that they were manufactured in the same batch or are derived from the same unit of production, as the case may be.

3. The immediate container, if any, of a cosmetic product purchased by an enforcement authority shall not have been opened by, on behalf of or at the request of the enforcement authority before the purchase takes place and the container shall not thereafter be opened except in accordance with paragraph 5.3 of Part I of Annex A and paragraph 1.2 of Part II of Annex A.

4. As soon as an enforcement authority has purchased a cosmetic product, the officer effecting the purchase shall—

(a) either—

- (i) place a seal on the product’s container or outer packaging, or
- (ii) place the product in a container and forthwith place a seal on that container,

in such a way that the product’s immediate container cannot be opened or (in the case of a product which was not in a container when it was purchased) the product cannot be touched without (in either case) the seal being broken in such a manner that it would be apparent thereafter that it had been broken, and

(b) attach to the product a label indicating—

- (i) the name of the product,
- (ii) the date, time and place at which the product was purchased,
- (iii) his own name, and
- (iv) the name of the enforcement authority making the purchase.

(a) O.J. No. L383, 31.12.1980, p. 27.

(b) O.J. No. L185, 30.6.1982, p. 1.

(c) O.J. No. L291, 24.10.1983, p. 9.

5.— (1) Subject to sub-paragraph (2) below, the provisions of Part I of Annex A, other than paragraphs 3.1, 3.2 and 4, and of Part II of Annex A, other than paragraph 1.4, shall be complied with in the sampling of cosmetic products and the laboratory preparation of test portions.

(2) Where, because of the way in which a cosmetic product is put up for sale, it is not practicable for Part II of Annex A to be complied with in relation to it, it shall be prepared for testing in accordance with good analytical practice, and the person so preparing it shall record in writing the method of preparation which he has used.

6.— (1) Any test to determine whether a cosmetic product contains a significant amount of free sodium hydroxide or free potassium hydroxide shall be carried out in accordance with paragraphs 1 to 4 of Part III of Annex A.

(2) Any test to determine the amount of free sodium hydroxide or free potassium hydroxide in a hair straightener product or a nail cuticle solvent product shall be carried out in accordance with paragraphs 1, 2, 3 and 5 of Part III of Annex A.

(3) Any test to determine whether a hair-care product contains oxalic acid or any alkaline salt of oxalic acid or to determine the amount of such a substance in a hair-care product shall, subject to the limitation specified in the second sentence of paragraph 1 of Part IV of Annex A, be carried out in accordance with the said Part IV.

(4) Any test to determine the amount of chloroform in toothpaste shall, subject to the limitation specified in the second sentence of paragraph 1 of Part V of Annex A, be carried out in accordance with the said Part V.

(5) Any test to determine the amount of zinc chloride, zinc sulphate or zinc 4-hydroxybenzenesulphonate by virtue of their zinc contents in a cosmetic product shall be carried out in accordance with Part VI of Annex A, and shall take into account paragraph 11 of Part VII of Annex A.

(6) Any test to determine whether a cosmetic product contained in an aerosol dispenser or a cream, emulsion, lotion, gel or oil intended to be applied to the skin contains 4-hydroxybenzenesulphonic acid, or to determine the amount of that acid in such a product, shall be carried out in accordance with Part VII of Annex A.

(7) Any test to determine whether a hair-care product contains persulphate, bromate or hydrogen peroxide shall be carried out in accordance with Part A of Part I of Annex B.

(8) Any test to determine whether a hair-care product contains barium peroxide shall be carried out in accordance with Part B of Part I of Annex B.

(9) Any test to determine the amount of hydrogen peroxide in a hair-care product shall be carried out in accordance with Part C of Part I of Annex B.

(10) Any test to determine whether a hair-dye contains any of the oxidation colorants specified in paragraph 1 of Part II of Annex B, or to determine the amount of such a substance in a hair-dye, shall be carried out in accordance with the said Part II.

(11) Any test to determine whether a cosmetic product contains nitrite, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with Part III of Annex B.

(12) Any test to determine whether a cosmetic product contains free formaldehyde, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with Part IV of Annex B.

(13) Any test to determine the amount of resorcinol in a shampoo or hair lotion shall, subject to the limitation specified in the second sentence of paragraph 1 of Part V of Annex B, be carried out in accordance with the said Part V.

(14) Any test to determine the amount of methanol in relation to ethanol or propan-2-ol in a cosmetic product shall be carried out in accordance with Part VI of Annex B.

(15) Any test to determine the amount of dichloromethane or 1,1,1-trichloroethane in a cosmetic product shall be carried out in accordance with paragraphs 1 to 10 of that part of Annex C which is headed "Determination of dichloromethane and 1,1,1-trichloroethane".

(16) Any test to determine whether a cosmetic product contains quinolin-8-ol or bis (8-hydroxyquinolinium) sulphate, or to determine the amount of such a substance in a cosmetic product, shall be carried out in accordance with paragraphs 1 to 9 of that part of Annex C which is headed "Identification and determination of quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate".

(17) Any test to determine the amount of ammonia in a cosmetic product shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of ammonia".

(18) Any test to determine whether a cosmetic product contains nitromethane, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with paragraphs 1 to 7 of that part of Annex C which is headed "Identification and determination of nitromethane".

(19) Any test to determine whether a hair waving, hair straightening or depilatory product contains mercaptoacetic acid, or to determine the amount of that substance in such a product, shall be carried out in accordance with paragraphs 1 to 6 of that part of Annex C which is headed "Identification and determination of mercaptoacetic acid in hair-waving, hair-straightening and depilatory products".

(20) Any test to determine whether a cosmetic product contains hexachlorophene (INN) shall be carried out in accordance with paragraphs 1 to 7 of Part A of that part of Annex 6 which is headed "Identification and determination of hexachlorophene".

(21) Any test to determine the amount of hexachlorophene (INN) in a cosmetic product shall be carried out in accordance with paragraphs 1 to 9 of Part B of that part of Annex C which is headed "Identification and determination of hexachlorophene".

(22) Any test to determine the amount of tosylchloramide sodium (INN) in a cosmetic product shall be carried out in accordance with paragraphs 1 to 9 of that part of Annex C which is headed "Quantitative determination of tosylchloramide sodium (INN) (chloramine-T)".

(23) Any test to determine the total amount of fluorine in dental creams shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of total fluorine in dental creams".

(24) Any test to determine whether a cosmetic product contains organomercury compounds shall be carried out in accordance with paragraphs 1 to 4 of Part A of that

part of Annex C which is headed "Identification and determination of organomercury compounds".

(25) Any test to determine the amount of organomercury compounds in a cosmetic product shall be carried out in accordance with paragraphs 1 to 7 of Part B of that part of Annex C which is headed "Identification and determination of organomercury compounds".

(26) Any test to determine the amount of alkali sulphides or alkaline earth sulphides in a cosmetic product shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of alkali and alkaline earth sulphides".

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations revoke and re-enact with amendments the Cosmetic Products Regulations 1978 and the Cosmetic Products (Amendment) Regulations 1983. The Regulations implement Council Directives No. 76/768/EEC, No. 82/368/EEC and No. 83/574/EEC and Commission Directives No. 80/1335/EEC, No. 82/147/EEC, No. 82/434/EEC, No. 83/191/EEC, No. 83/341/EEC, No. 83/496/EEC and No. 83/514/EEC relating to cosmetic products, and, as permitted by the Directives, impose certain additional requirements relating to the composition of cosmetic products. The Regulations are made principally under the Consumer Safety Act 1978, but also under the Consumer Protection Act 1961 and the European Communities Act 1972.

The changes of substance—

- (1) impose a requirement that a cosmetic product may contain only preservatives listed in Schedule 5, in certain circumstances subject to restrictions (Regulation 6(6) and Schedule 5);
- (2) impose a requirement that a cosmetic product may contain only UV filters listed in Schedule 6, in certain circumstances subject to restrictions (Regulation 6(7) and Schedule 6);
- (3) permit the Secretary of State to authorise the use of any substance in a cosmetic product, subject to conditions (Regulation 7);
- (4) make provision for certain particulars to be marked on containers of cosmetic products which contain certain preservatives or UV filters (Regulation 8(1)(d) and (e) and Schedules 5 and 6);
- (5) allow in relation to market research experiments certain relaxations from the marking requirements of Regulation 8(1) (Regulation 8(1)); and
- (6) make further provision for the procedure to be followed in obtaining samples of cosmetic products in order to test them, for the preparation of such samples for testing and for certain test methods (Regulation 11 and Schedule 7).

Certain modifications are made to the substances listed in Schedules 1 and 2 and to the colouring agents listed in Schedules 3 and 4.

Certain provisions of Trade Descriptions Act 1968 (c.29) are no longer disappplied, since, by virtue of Section 2(4)(g) of that Act, any description or mark applied to goods in pursuance of the Consumer Safety Act 1978 is deemed not to be a trade description.

The Cosmetic Products Regulations 1978 are amended by the insertion of a new Regulation 2A providing that those Regulations shall not apply in relation to the sale or possession for sale of cosmetic products which satisfy the requirements of these Regulations (Regulation 2). This amendment comes into operation on 28 August 1984. The Cosmetic Products Regulations 1978 and the Cosmetic Products (Amendment) Regulations 1983 are revoked—

- (a) In relation to first suppliers, on 1st January 1986; and
- (b) In relation to all other suppliers, on 1st January 1988.

These Regulations come into operation—

- (a) In relation to first suppliers, on 1st January 1986 (1st January 1987 in the case of Regulations 6(7) and 8(1)(e) which relate to UV filters); and
- (b) In relation to all other suppliers, on 1st January 1988 (1st January 1989 in the case of Regulations 6(7) and 8(1)(e) which relate to UV filters).

(Regulations 1(3), (5) and (6) and 3).

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colourists, PO Box No. 244, 82, Grattan Road, Bradford BD1 2JB.

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