No. S 80

MEDICINES ORDER, 2007

MEDICINES (COSMETIC PRODUCTS) REGULATIONS, 2007

ARRANGEMENT OF REGULATIONS

Regulation

MEDICINES ORDER, 2007

MEDICINES (COSMETIC PRODUCTS) REGULATIONS, 2007

In exercise of the power conferred by section 81 of the Medicines Order, 2007, the Minister of Health, with the approval of His Majesty the Sultan and Yang Di-Pertuan, hereby makes the following Regulations —

PART I

PRELIMINARY

Citation and commencement.

1. These Regulations may be cited as the Medicines (Cosmetic Products) Regulations, 2007 and shall commence on the 1st. January, 2008.

Interpretation.

2. In these Regulations, unless the context otherwise requires —

"Authority" means the Authority established under section 5 of the Medicines Order, 2007;

"cosmetic product" means any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and correcting body odours, protecting them or keeping them in good condition or all or any of those purposes;

"importer", in relation to a cosmetic product, means any person who imports or who procures or arranges for the import of any cosmetic product into Brunei Darussalam for supply in Brunei Darussalam;

"manufacturer" means any person engaged in any process carried out in the course of making any cosmetic product in Brunei Darussalam for supply in Brunei Darussalam.

Application.

3. These Regulations shall not apply to a cosmetic product that is —

(a) imported into Brunei Darussalam solely for re-export; or

(b) manufactured in Brunei Darussalam solely for export.

PART II

APPOINTMENT OF AUTHORITY, ASSISTANTS ETC.

Appointments.

4. (1) The Authority may delegate to the Director of Pharmaceutical Services the exercise of all or any of the powers and the performance of its duties under these Regulations.

(2) The Authority may authorise or appoint any person to assist in the exercise of its powers, duties and functions under these Regulations.

(3) Any person delegated under sub-regulation (1) or authorised or appointed under sub-regulation (2) shall be deemed to be a public servant for the purposes of the Penal Code (Chapter 22).

PART III

SUPPLY OF COSMETIC PRODUCTS

Notification to Authority of supply of cosmetic products.

5. (1) The importer or manufacturer of a cosmetic product shall not —

(a) supply that cosmetic product in Brunei Darussalam unless he has notified the Authority of his intention to supply that cosmetic product in Brunei Darussalam; or

(b) continue to supply that cosmetic product in Brunei Darussalam after the expiry of one year from the most recent notification made in respect of that cosmetic product, unless he has submitted a further notification to the Authority of his intention to continue supplying that cosmetic product in Brunei Darussalam.

(2) The Authority has the right to suspend or cancel any notification for the purposes of sub-regulation (1) if the product is suspected or found to cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

(3) A notification for the purposes of sub-regulation (1) shall be submitted to the Authority in such form and manner as the Authority may require and shall be accompanied by —

(a) such particulars, information, documents and samples as the Authority may require; and

(b) if required by the Authority, a statutory declaration by the applicant verifying any information contained in or related to the notification.

(4) Any person who, in submitting a notification for the purposes of sub-regulation (1) —

(a) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

(b) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

PART IV

SAFETY REQUIREMENTS

Safety requirements.

6. (1) The manufacturer, his authorised agent or any other person responsible for placing the product on the market shall not supply a cosmetic product that cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the market.

(2) The provision of such warnings in sub-regulation (1) shall not, in any event, exempt any person from compliance with the other requirements laid down in these Regulations.

PART V

INGREDIENT LISTING

Contents of cosmetic products.

7. (1) A person shall not supply a cosmetic product which contains any substance that is listed in Part I of the First Schedule to these Regulations unless the presence of such substance is —

(a) in trace amount; and

(b) technically unavoidable in good manufacturing practice.

(2) A person shall not supply a cosmetic product which contains any substance that is listed in the second column of Part II of the First Schedule to these Regulations unless —

(a) the cosmetic product is of a type listed in the third column of that Part of that Schedule;

(b) the substance as contained in the cosmetic product does not exceed the appropriate limit as specified in the fourth column of that Part of that Schedule; and

(c) the cosmetic product complies with the other relevant requirements as specified in the fifth column of that Part of that Schedule.

(3) A person shall not supply a cosmetic product, other than a cosmetic product intended solely to colour hair, which contains any colouring agent unless that colouring agent —

(a) is listed in Part III of the First Schedule to these Regulations; and

(b) is in accordance with the requirements as specified in that Part of that Schedule.

(4) A person shall not supply a cosmetic product which contains any preservative unless —

(a) that preservative is listed in the second column of Part IV of the First Schedule to these Regulations;

(b) that preservative as contained in the cosmetic product does not exceed the appropriate limit as specified in the third column of that Part of that Schedule; and

(c) the cosmetic product complies with the other relevant requirements as specified in the fourth column of that Part of that Schedule.

(5) A person shall not supply a cosmetic product which contains any ultraviolet (UV) filter unless —

(a) the ultraviolet (UV) filter is listed in the second column of Part V of the First Schedule to these Regulations;

(b) the ultraviolet (UV) filter as contained in the cosmetic product does not exceed the appropriate limit as specified in the third column of that Part of that Schedule; and

(c) the cosmetic product complies with the other relevant requirements as specified in the fourth column of that Part of that Schedule.

Labelling of cosmetic products.

8. (1) No person shall supply any cosmetic product unless the cosmetic product has a label that sets out the information in the Second Schedule to these Regulations and the information required thereunder, shall be in legible and visible lettering.

(2) All information on the label of a cosmetic product shall be provided in the English language, the Malay language or both.

(3) All numbers, letters and symbols used in providing the information on the label of a cosmetic product shall be legible, permanent and prominent.

(4) If a symbol or code (whether in the form of a colour or otherwise) is used in providing the information on the label of a cosmetic product, an explanation of the symbol or colour shall be provided.

Misleading labelling.

9. No person shall supply any cosmetic product with a label which contains any statement, trademark, picture or other sign —

(a) to the effect, whether directly or indirectly, that the supply or use of the cosmetic product is being promoted or endorsed by the Authority; or

(b) that is likely to create an erroneous impression regarding the formulation, composition, quality or safety of the cosmetic product.

Product information.

10. (1) The person responsible for placing the cosmetic product in the market shall keep the following information or documents readily accessible to the Authority —

(a) the qualitative and quantitative composition of the product; in case of perfume compositions, the name and code number of the composition and the identity of the supplier;

(b) specifications of the raw materials and finished product;

(c) the method of manufacture complying with the good manufacturing practice as laid down in the Third Schedule to these Regulations;

(d) assessment of the safety for human health of the finished product, based on its ingredients, its chemical structure and its level of exposure;

(e) existing data on undesirable effects on human health resulting from the use of the cosmetic product;

(f) supporting data for claimed benefits of cosmetic products should be made available to justify the nature of its effect;

(g) the available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the certificate of analysis; and

(h) the criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products, methods for checking compliance with those criteria or both.

(2) The information referred to in sub-regulation (1) shall be made in the English language, the Malay language or both.

(3) The Authority may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the Authority which shall ensure that this information is used only for the purposes of such treatment.

PART VI

ADVERTISEMENT OF COSMETIC PRODUCTS

Advertisement of cosmetic products.

11. No person shall advertise any cosmetic product or cause any cosmetic product to be advertised —

(a) with any claim, whether expressly or by implication, that the cosmetic product has a therapeutic benefit or can be used for a therapeutic purpose; or

(b) with any claim which is likely to create an erroneous impression regarding the formulation, composition, quality or safety of the cosmetic product.

PART VII

ADDITIONAL DUTIES AND OBLIGATIONS

Reporting of defects and adverse events to the Authority.

12. (1) The supplier of a cosmetic product —

(a) upon becoming aware of any event or other occurrence that concerns any adverse effect arising from the use of the cosmetic product, shall —

(i) if the adverse effect has caused death or is life-threatening —

(A) inform the Authority of the event or occurrence no later than 7 days after the supplier becomes aware of the event or occurrence; and

(B) submit a detailed report to the Authority within 8 days after the initial report; or

(ii) if the adverse effect has resulted in any person being hospitalised or has caused any persistent or significant disability or incapacity in any person, submit a detailed report on the event or occurrence to the Authority no later than 15 days after the supplier becomes aware of the event or occurrence; and

(b) upon becoming aware of any event or other occurrence that reveals any defect in the cosmetic product, shall —

(i) if the defect may cause death or may be life-threatening —

(A) inform the Authority of the event or occurrence no later than 7 days after the supplier becomes aware of the event or occurrence; and

(B) submit a detailed report to the Authority within 8 days of the initial report; or

(ii) if the defect may result in any person being hospitalised or may cause any persistent or significant disability or incapacity in any person, submit a detailed report of the event or occurrence to the Authority no later than 15 days after the supplier becomes aware of the event or occurrence.

(2) The reports referred to under sub-regulation (1) shall be in such form and manner, and shall contain such information in relation to the defect or adverse event, as the Authority may require.

PART VIII

GENERAL

Special cases.

13. The Authority may provisionally prohibit the marketing of a cosmetic product in Brunei Darussalam or subject it to special conditions if, on the basis of a substantiated justification, the cosmetic product, although complying with the requirements of these Regulations, represents a hazard to health or for reasons specific to religious or cultural sensitivity.

Offences by bodies corporate.

14. Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of that body or of any person who was purporting to act in any such capacity, he, as well as the body corporate, is also guilty of that offence and liable to be proceeded against and punished accordingly.

Transitional.

15. Notwithstanding the provisions of these Regulations, the Authority may, for a period of 3 years from the date of commencement of these Regulations, authorise the marketing in Brunei Darussalam of cosmetic products which do not conform to the requirements of these Regulations.

Penalty for offences not otherwise provided for.

16. Any person who commits any offence against these Regulations, for which no other penalty is provided, is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

Amendment of Schedules.

17. The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, by notification in the *Gazette,* amend any of the Schedules to these Regulations.

FIRST SCHEDULE (regulation 7(1))

Part 1

List of substances which must not form part of the composition of cosmetic products

Ref. No.	Substance
A1136	Aminophylline
A1137	Theophylline
A1138	Methylene chloride (Dichloromethane)
A1139	Chlorofluorocarbons
A1140	Diethylene glycol when used in products intended to come into contact with the mucous membranes of the oral cavity
1	N-5-Chlorobenzoxazol-2-yl acetamide
2	β-Acetoxyethyl trimethylammonium hydroxide (acetylcholine and its salts)
3	Deanol aceglumate
4	Spironolactone
5	[4-(4-Hydroxy-3-iodophenoxy)-3, 5-diodophenyl] acetic acid and its salts
6	Methotrexate
7	Aminocaproic acid and its salts
8	Cinchophen, its salts, derivatives and salts of these derivatives
9	Thyropropic acid and its salts
10	Trichloroacetic acid
11	*Aconitum napellus* L. (leaves, roots and galenical preparations)
12	Aconitine (principal alkaloid of *Aconitum napellus* L.) and its salts
13	*Adonis vernalis* L. and its preparations
14	Epinephrine
15	*Rauwolfia serpentina* alkaloids and their salts
16	Alkyne alcohols, their esters, ethers and salts
17	Isoprenaline
18	Allyl isothiocyanate
19	Alloclamide and its salts
20	Nalorphine, its salts and ethers

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
21	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution (69) 2 of the Council of Europe
22	Aniline, its salts and its halogenated and sulphonated derivatives
23	Betoxycaine and its salts
24	Zoxazolamine
25	Procainamide, its salts and derivatives
26	Benzidine
27	Tuaminoheptane, its isomers and salts
28	Octodrine and its salts
29	2-Amino-1, 2-bis (4-methoxyphenyl) ethanol and its salts
30	1, 3-dimethylpentylamine and its salts
31	4-Aminosalicylic acid and its salts
32	Toluidines, their isomers, salts and halogenated and sulphonated derivatives
33	Xylidines, their isomers, salts and halogenated and sulphonated derivatives
34	Imperatorin (9-(3-methylbut-2-enyloxy) furo(3, 2-g) chromen-7-one)
35	*Ammi majus* (Bishop's weed) and its galenical preparations
36	2, 3-Dichloro-2-methylbutane
37	Substances with androgenic effect
38	Anthracene oil
39	Antibiotics
41	*Apocynum cannabinum* L. and its preparations
42	Apomorphine (5, 6, 6a, 7-tetrahydro-6-methyl-4H-dibenzo (de, g)-quinoline-10, 11-dihydric alcohol) and its salts
43	Arsenic and its compounds
44	*Atropa belladonna* L. and its preparations
45	Atropine, its salts and derivatives
46	Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Part II, and lakes, salts and pigments prepared from the colouring agents listed with the reference (3) in Part III and Annex IV, Part 2 of the ASEAN Cosmetic Directive

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
47	Benzene
48	Benzimidazol-2(3H)-one
49	Benzazepines and benzadiazepines
50	1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts
51	2, 2, 6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts
52	Isocarboxazide
53	Bendroflumethiazide and its derivatives
54	Beryllium and its compounds
55	Bromine, elemental
56	Bretylium tosilate
57	Carbromal
58	Bromisoval
59	Brompheniramine and its salts
60	Benzilonium bromide
61	Tetrylammonium bromide
62	Brucine
63	Tetracaine and its salts
64	Mofebutazone
65	Tolbutamide
66	Carbutamide
67	Phenylbutazone
68	Cadmium and its compounds
69	Cantharides, *Cantharis vesicatoria*
70	(1R, 2S)-Hexahydro-1, 2-dimethyl-3, 6-epoxyphthalic anhydride (cantharidin)
71	Phenprobamate
72	Nitroderivatives of carbozol
73	Carbon disulphide
74	Catalase
75	Cephaeline and its salts
76	Chenopodium ambrosioides (essential oil)
77	2, 2, 2-Trichloroethane-1,1-diol

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
78	Chlorine
79	Chlorpropamide
80	Diphenoxylate hydrochloride
81	4-Phenylazophenylene-1, 3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82	Chlorzoxazone
83	2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)
84	Chlorprothixene and its salts
85	Clofenamide
86	N, N-bis (2-chloroethyl) methylamine N-oxide and its salts
87	Chlormethine and its salts
88	Cyclophosphamide and its salts
89	Mannomustine and its salts
90	Butanilicaine and its salts
91	Chlormezanone
92	Triparanol
93	2-[2-(4-Chlorophenyl)-2-phenylacetyl] indane 1, 3-dione (chlorophacinone-ISO)
94	Chlorphenoxamine
95	Phenaglycodol
96	Chloroethane
97	Chromium; chromic acid and its salts
98	*Calviceps purpurea* Tul., its alkaloids and galenical preparations
99	*Conium maculatum* L. (fruit, powder, galenical preparations)
100	Glycyclamide
101	Cobalt benzenesulphonate
102	Colchicine, its salts and derivatives
103	Colchicoside and its derivatives
104	*Colchicum autumnale* L. and its galenical preparations
105	Convallatoxin
106	*Anamirta cocculus* L. (fruit)
107	*Croton tiglium* (oil)
108	1-Butyl-3-(N-crotonoylsulphanilyl) urea

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
109	Curare and curarine
110	Synthetic curarizants
111	Hydrogen cyanide and its salts
112	2-α-Cyclohexylbenz,yl (N, N, N', N'-tetraethyl) trimethylenediamine phenetamine
113	Cyclomenol and its salts
114	Sodium hexacyclonate
115	Hexapropymate
116	Dextropropoxyphene
117	O.O-Diacetyl-N-allyl-N-normorphine
118	Pipazetate and its salts
119	5-(α, β-Dibromophenethyl)-5-methylhydantoin
120	N, N'-Pentamethylenebis (trimethylammonium) salts, e.g. Pentamethonium bromide
121	N, N'-[(Methylimino)diethylene]bis(ethyldimethylammonium) salts, e.g. azamethonium bromide
122	Cyclarbamate
123	Clofenotane; DDT (ISO)
124	Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*
125	Dichloroethanes (ethylene chlorides)
126	Dichloroethylenes (acetylene chlorides)
127	Lysergide and its salts
128	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts
129	Cinchocaine and its salts
130	3-Diethylaminopropyl cinnamate
131	O, O-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)
132	[Oxalylbisiminoethylene)] bis[(o-chlorobenzyl) diethylammonium] salts, e.g. ambenomium chloride
133	Methyprylon and its salts
134	Digitaline and all heterosides of *Digitalis purpurea* L.
135	7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propy] theophylline (xanthinol)
136	Dioxethedrin and its salts

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
137	Piprocurarium
138	Propyphenazone
139	Tetrabenazine and its salts
140	Captodiame
141	Mefeclorazine and its salts
142	Dimethylamine
143	1, 1-Bis (dimethylaminomethyl) propyl benzoate (amydricaine, alypine) and its salts
144	Methapyrilene and its salts
145	Metamfepramone and its salts
146	Amitriptyline and its salts
147	Metformin and its salts
148	Isosorbide dinitrate
149	Malononitrile
150	Succinonitrile
151	Dinitrophenol isomers
152	Inproquone
153	Dimevamide and its salts
154	Diphenylpyraline and its salts
155	Sulfinpyrazone
156	N-(3-Carbamoyl-3, 3-diphenylpropyl)-N, N-diisopropylmethylammonium salts, e.g. isopropamide iodide
157	Benactyzine
158	Benzatropine and its salts
159	Cyclizine and its salts
160	5, 5-Diphenyl-4-imidazolidone
161	Probenecid
162	Disulfiram; thiram (ISO)
163	Emetine, its salts and derivatives
164	Ephedrine and its salts
165	Oxanamide and its derivatives
166	Eserine or physostigmine and its salts

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
167	Esters of 4-aminobenzoic acid, with a free amino group, with the exception of that given in Annex VII Part 2 of the ASEAN Cosmetic Directive
168	Choline salts and their esters, e.g. choline chloride
169	Caramiphen and its salts
170	Diethyl 4-nitrophenyl phosphate
171	Metethoheptazine and its salts
172	Oxpheneridine and its salts
173	Ethoheptazine and its salts
174	Metheptazine and its salts
175	Methylphenidate and its salts
176	Doxylamine and its salts
177	Tolboxane
178	4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol
179	Parethoxycaine and its salts
180	Fenozolone
181	Glutethimide and its salts
182	Ethylene oxide
183	Bemegride and its salts
184	Valnoctamide
185	Haloperidol
186	Paramethasone
187	Fluanisone
188	Trifluperidol
189	Fluoresone
190	Fluorouracil
191	Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Part II
192	Furfuryltrimethylammonium salts, e.g. furtrethonium iodide
193	Galantamine
194	Progestogens
195	1, 2, 3, 4, 5, 6-Hexachlorocyclohexane (BHC-ISO) (lindane)

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
196	(1R, 4S, 5R, 8S)-1, 2, 3, 4, 10, 10-Hexachloro-6, 7-epoxy-1, 4, 4a, 5, 6, 7, 8, 8a-octahydro-1, 4:5, 8-dimethanonaphthalene (endrin-ISO)
197	Hexachloroethane
198	(1R, 4S, 5R, 8S)-1, 2, 3, 4, 10, 10-Hexachloro-1, 4, 4a, 5, 8, 8a-hexahydro-1, 4:5, 8-dimethanonaphthalene (isodrin-ISO)
199	Hydrastine, hydrastinine and their salts
200	Hydrazides and their salts
201	Hydrazine, its derivatives and their salts
202	Octamoxin and its salts
203	Warfarin and its salts
204	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
205	Methocarbamol
206	Propatylnitrate
207	4, 4'-Dihydroxy-3, 3'-(3-methylthiopropylidene) dicoumarin
208	Fenadiazole
209	Nitroxoline and its salts
210	Hyoscyamine, its salts and derivative
211	*Hyoscyamus niger* L. (leaves, seeds, powder and galenical preparations)
212	Pemoline and its salts
213	Iodine
214	Decamethylenebis (trimethylammonium) salts, e.g. decamethonium bromide
215	Ipecacuanha (*Cephaelis ipecacuanha* Brot. and related species) (roots, powder and galenical preparations)
216	(2-isopropylpent-4-enoyl)urea (apronalide)
217	a-Santonin [(3S, 5aR, 9bS)-3, 3a, 4, 5, 5a, 9b-hexahydro-3, 5a, 9-trimethylnaphto [1, 2-b] furan-2, 8-dione]
218	*Lobelia inflata* L. and its galenical preparations
219	Lobeline and its salts
220	Barbiturates
221	Mercury and its compounds except those special cases included in Part IV

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
222	3, 4, 5-Trimethoxyphenethylamine and its salts
223	Metaldehyde
224	2-(4-Allyl-2-methoxyphenoxy)-N, N-diethylacetamide and its salts
225	Coumetarol
226	Dextromethorphan and its salts
227	2-Methylheptylamine and its salts
228	Isometheptene and its salts
229	Mecamylamine
230	Guaifenesin
231	Dicoumarol
232	Phenmetrazine, its derivatives and salts
233	Thiamazole
234	3, 4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H, 5H, pyrano(3, 2-c)-(1) benzopyran-5-one (cyclocoumarol)
235	Carisoprodol
236	Meprobamate
237	Tefazoline and its salts
238	Arecoline
239	Poldine methylsulfate
240	Hydroxyzine
241	2-Naphthol
242	1-and 2-Naphthylamines and their salts
243	3-(1–Naphthyl)-4-hydroxycoumarin
244	Naphazoline and its salts
245	Neostigmine and its salts (e.g. neostigmine bromide)
246	Nicotine and its salts
247	Amyl nitrites
248	Inorganic nitrites, with the exception of sodium nitrite
249	Nitrobenzene
250	Nitrocresols and their alkali metal salts
251	Nitrofurantoin
252	Furazolidone
253	Propane-1 2, 3-triyl trinitrate

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
254	Acenocoumarol
255	Alkali pentacyanonitrosylferrate (2-)
256	Nitrostilbenes, their homologues and their derivatives
257	Noradrenaline and its salts
258	Noscapine and its salts
259	Guanethidine and its salts
260	Oestrogens
261	Oleandrin
262	Chlortalidone
263	Pelletierine and its salts
264	Pentachloroethane
265	Pentaerithrityl tetranitrate
266	Petrichloral
267	Octamylamine and its salts
268	Picric acid
269	Phenacemide
270	Difencloxazine
271	2-Phenylindan-1, 3-dione (phenindione)
272	Ethylphenacemide
273	Phenprocoumon
274	Fenyramidol
275	Triamterence and its salts
276	Tetraethyl pyrophosphate; TEPP (ISO)
277	Tritolyl phosphate
278	Psilocybine
279	Phosphorus and metal phosphides
280	Thalidomide and its salts
281	*Physostigma venenosum* Balf.
282	Picrotoxin
283	Pilocarpine and its salts
284	α-Piperidin-2-yl benzyl acetate laevorotatory threoform (Levophacetoperane) and its salts

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
285	Pipradrol and its salts
286	Azacyclonol and its salts
287	Bietamiverine
288	Butopiprine and its salts
289	Lead and its compounds
290	Coniine
291	*Prunus laurocerasus* L. ('cherry laurel water')
292	Metyrapone
293	Radioactive substances, as defined by Directive 96/29/Euratom (1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation
294	*Juniperus sabina* L. (leaves, essential oil and galenical preparations)
295	Hyoscine, its salts and derivatives
296	Gold salts
297	Selenium and its compounds with the exception of selenium disulphide under the conditions set out under the reference No. 49 in Part II
298	*Solanum nigrum* L. and its galenical preparations
299	Sparteine and its salts
300	Glucocorticoids
301	*Datura stramonium* L. and its galenical preparations
302	Strophantines, their aglucones and their respective derivatives
303	Strophantus species and their galenical preparations
304	Strychnine and its salts
305	Strychnos species and their galenical preparations
306	Narcotics, natural and synthetic
307	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH2 groups) and their salts
308	Sultiame
309	Neodymium and its salts
310	Thiotepa
311	*Pilocarpus jaborandi Holmes* and its galenical preparations

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
312	Tellurium and its compounds
313	Xylometazoline and its salts
314	Tetrachloroethylene
315	Carbon Tetrachloride
316	Hexaethyl tetraphosphate
317	Thallium and its compounds
318	*Thevetia neriifolia* Juss. glycoside extract
319	Ethionamide
320	Phenothiazine and its compounds
321	Thiourea and its derivatives with the exception of the one listed in Part II
322	Mephenesin and its esters
323	Vaccines, toxins or serums listed in the Annex to the Second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products
324	Tranylcypromine and its salts
325	Trichloronitromethane (chloropicrine)
326	2, 2, 2-Tribromoethanol (tribromoethyl alcohol)
327	Trichlormethine and its salts
328	Tretamine
329	Gallamine triethiodide
330	Urginea scilla Stern. and its galenical preparations
331	Veratrine, its salts and galenical preparations
332	*Schoenoocaulon officinale* Lind. (seeds and galenical preparations)
333	*Veratrum* Spp. and their preparations
334	Vinyl chloride monomer
335	Ergocalciferol and cholecalciferol (vitamins D2 and D3)
336	Salts of o-alkyldithiocarbonic acids
337	Yohimbine and its salts
338	Dimethyl sulfoxide
339	Diphenhydramine and its salts
340	4-tert-Butylphenol

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
341	4-tert-Butylpyrocatechol
342	Dihydrotachysterol
343	Dioxane
344	Morpholine and its salts
345	Pyrethrum album L. and its galenical perparations
346	2-{4-Methoxybenzyl-N-{2-pyridyl}amino}ethyldimethylamine maleate
347	Tripelennamine
348	Tetrachlorosalicylanilides
349	Dichlorosalicylanilides
350	Tetrabromosalicylanilides
351	Dibromosalicylanilides
352	Bithionol
353	Thiuram monosulphides
354	Thiuram disulphides
355	Dimethylformamide
356	4-Phenylbut-3-en-2-one
357	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used
358	Furocoumarines (e.g. trioxysalan*, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used In sun protection and in bronzing products, furocoumarines shall be below 1mg/kg
359	Oil from the seeds of *Laurus nobilis* L.
360	Safrole except for normal content in the natural essences used and provided the concentration does not exceed: ■ 100 ppm in the finished product ■ 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children.
361	5, 5'-Di-isopropyl-2, 2'-dimethylbiphenyl-4, 4'-diyl dihypoiodite
362	3'-ethyl-5', 6', 7, 8'-tetrahydro-5', 5', 8', 8'-tetramethyl-2'-acetonaphthone, or 7-acetyl-6-ethyl-1, 1, 4, 4-tetramethyl-1, 2, 3, 4-tetrahydronaphthalen

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
363	o-Phenylenediamine and its salts
364	4-Methyl-m-phenylenediamine and its salts
365	Aristolochic acid and its salts, *Aristolochia* spp. and their preparations
366	Chloroform
367	2, 3, 7, 8,-Tetra chlorodibenzo-p-dioxin
368	2, 6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)
369	Pyrithione sodium (INNM)
370	N-(Trichloromethylthio)-4-cyclohexene-1, 2-dicarboximide (Captan)
371	2, 2 '-Dihydroxy-3, 3', 5, 5', 6, 6'--hexachlorodiphenylmethane (Hexachlorophene)
372	6-(Piperidinyl)-2, 4-pyrimidinediamine-3-oxide (minoxidil) and its salts
373	3, 4', 5-Tribromosalicylanilide
374	*Phytolacca* Spp. and their preparations
375	Tretinoin (retinoic acid and its salts)
376	1-Methoxy-2, 4-diaminobenzene (2, 4-diaminoanisole-Cl 76050) and their salts
377	1-Methoxy-2, 5-diaminobenzene (2, 5 -diaminoanisole) and their salts
378	Colouring agent CI 12140
379	Colouring agent CI 26105
380	Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2
381	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
382	Entry deleted
383	2-Amino-4-nitrophenol
384	2-Amino-5-nitrophenol
385	11α-Hydroxypregn-4-ene-3, 20-dione and its esters
386	Colouring agent CI 42640
387	Colouring agent CI 13065
388	Colouring agent CI 42535

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
389	Colouring agent CI 61554
390	Anti-androgens of steroidal structure
391	Zirconium and its compounds, with the exception of the substances listed under reference number 50 in Part II, and the zirconium lakes, pigments or salts of the colouring agents listed in Part III
392	Entry deleted
393	Acetonitrile
394	Tetrahydrozoline and its salts
395	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in Part II No. 51
396	Dithio-2, 2'-bispyridine-dioxide 1, 1' (additive with trihydrated magnesium sulphate) - pyrithione disulphide + magnesium sulphate)
397	Colouring agent CI 12075 and its lakes, pigments and salts
398	Colouring agent CI 45170 and CI 45170:1
399	Lidocaine
400	1, 2-Epoxybutane
401	Colouring agent CI 15585
402	Strontium lactate
403	Strontium nitrate
404	Strontium polycarboxylate
405	Pramocaine
406	4-Ethoxy-m-phenylenediamine and its salts
407	2, 4-Diaminophenylethanol and its salts
408	Catechol
409	Pyrogallol
410	Nitrosamines
411	Secondary alkyl- and dialkanolamines and their salts
412	4-Amino-2-nitrophenol
413	2-Methyl-m-phenylenediamine
414	4-tert-Butyl-3-methoxy-2, 6-dinitrotoluene (Musk Ambrette)
415	Entry deleted
416	Cells, tissues or products of human origin

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
417	3, 3- Bis(4-hydroxyphenyl)phthalide (Phenolphthalein)
418	3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)
419	From the date referred to in Article 22(1) of Regulation (EC) No. 999/2001 of the European Parliament and of the Council (1), the specified risk materials as designated in Annex V to that Regulation, and ingredients derived there from. Until that date, the specified risk materials as designated in Annex XI Part A to regulation (EC) No. 999/2001, and ingredients derived there from. However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer: — Transesterification or hydrolysis at least 200 degrees C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters), — Saponification with NaOH 12M (glycerol and soap): — Batch process: at 95 degrees C for three hours or — Continuous process: at 140 degrees C, two bars (2 000 hPa) for eight minutes or equivalent conditions.
420	Crude and refined coal tars
421	1, 1, 3, 3, 5,-Pentamethyl-4, 6-dinitroindane (moskene)
422	5-tert-Butyl-1, 2, 3-trimethyl-4, 6-dinitrobenzene (musk tibetene).
423	Alanroot oil (*Inula helenium*) when used as a fragrance ingredient
424	Benzyl cyanide when used as a fragrance ingredient
425	Cyclamen alcohol when used as a fragrance ingredient
426	Diethyl maleate when used as a fragrance ingredient
427	Dihydrocoumarine when used as a fragrance ingredient
428	2, 4-Dihydroxy-3-methylbenzaldehyde when used as a fragrance ingredient
429	3, 7-Dimethyl-2-octen-1-ol (6, 7-Dihydrogeraniol) when used as a fragrance ingredient
430	4, 6-Dimethyl-8-tert-butylcoumarin when used as a fragrance ingredient

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
431	Dimethyl citraconate when used as a fragrance ingredient
432	7, 11-Dimethyl-4, 6, 10-dodecatrien-3-one, when used as a fragrance ingredient
433	6, 10-Dimethyl-3, 5, 9-undecatrien-2-one, when used as a fragrance ingredient
434	Diphenylamine, when used as a fragrance ingredient
435	Ethyl acrylate, when used as a fragrance ingredient
436	Fig leaf absolute (*Ficus carica*), when used as a fragrance ingredient
437	Trans-2-Heptenal, when used as a fragrance ingredient
438	Trans-2-Hexenal diethyl acetal, when used as a fragrance ingredient
439	Trans-2-Hexenal dimethyl acetal, when used as a fragrance ingredient
440	Hydroabietyl alcohol, when used as a fragrance ingredient
441	6-Isopropyl-2-decahydronaphthalenol, when used as a fragrance ingredient
442	7-Methoxycoumarin, when used as a fragrance ingredient.
443	4-(4-Methoxyphenyl)-3-butene-2-one, when used as a fragrance ingredient
444	1-(4-Methoxyphenyl)-1-penten-3-one, when used as a fragrance ingredient
445	Methyl trans-2-butenoate, when used as a fragrance ingredient
446	7-Methylcoumarin, when used as a fragrance ingredient
447	5-Methyl-2, 3-hexanedione, when used as a fragrance ingredient
448	2-Pentylidenecyclohexanone, when used as a fragrance ingredient
449	3, 6, 10-Trimethyl-3, 5, 9-undecatrien-2-one, when used as a fragrance ingredient
450	Verbena oil (*Lippia citriodora* Kunth.), when used as a fragrance ingredient
451	Methyleugenol (CAS No 93-15-2) except for normal content in the natural essences used and provided that the concentration does not exceed: (a) 0,01 % in fine fragrance (b) 0,004 % in eau de toilette

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
	(c) 0,002 % in fragrance cream (d) 0,001 % in rinse-off products (e) 0,0002 % in other leave-on products and oral hygiene products
452	6-(2-Chloroethyl)-6-(2-methoxyethoxy)-2, 5, 7, 10-tetraoxa-6-silaundecane
453	Cobalt dichloride
454	Cobalt sulphate
455	Nickel monoxide
456	Dinickel trioxide
457	Nickel dioxide
458	Trinickel disulphide
459	Tetracarbonylnickel
460	Nickel sulphide
461	Potassium bromate
462	Carbon monoxide
463	Buta-1, 3-diene
464	Isobutane, if it contains = 0,1 % w/w Butadiene
465	Butane, if it contains = 0,1 % w/w Butadiene
466	Gases (petroleum), C3-4, if they contain > 0,1 % w/w Butadiene
467	Tail gas (petroleum), catalytic cracked distillate and catalytic cracked naphtha fractionation absorber, if it contains > 0,1 % w/w Butadiene
468	Tail gas (petroleum), catalytic polymn. naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene
469	Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene
470	Tail gas (petroleum), cracked distillate hydrotreater stripper, if it contains > 0,1 % w/w Butadiene
471	Tail gas (petroleum), gas oil catalytic cracking absorber, if it contains > 0,1 % w/w Butadiene
472	Tail gas (petroleum), gas recovery plant, if it contains > 0,1 % w/w Butadiene
473	Tail gas (petroleum), gas recovery plant deethaniser, if it contains > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
474	Tail gas (petroleum), hydrodesulfurised distillate and hydrodesulfurised naphtha fractionator, acid-free, if it contains > 0,1 % w/w Butadiene
475	Tail gas (petroleum), hydrodesulfurised vacuum gas oil stripper, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene
476	Tail gas (petroleum), isomerised naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene
477	Tail gas (petroleum), light straight-run naphtha stabiliser, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene
478	Tail gas (petroleum), straight-run distillate hydrodesulferised, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene
479	Tail gas (petroleum), propane-propylene alkylation feed prep deethaniser, if it contains > 0,1 % w/w Butadiene
480	Tail gas (petroleum), vacuum gas oil hydrodesulferised, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene
481	Gases (petroleum), catalytic cracked overheads, if they contain > 0,1 % w/w Butadiene
482	Alkanes, C1-2, if they contain > 0,1 % w/w Butadiene
483	Alkanes, C2-3, if they contain > 0,1 % w/w Butadiene
484	Alkanes, C3-4, if they contain > 0,1 % w/w Butadiene
485	Alkanes, C4-5, if they contain > 0,1 % w/w Butadiene
486	Fuel-gases, if they contain > 0,1 % w/w Butadiene
487	Fuel gases, crude oil distillates, if they contain > 0,1 % w/w Butadiene
488	Hydrocarbons, C3-4, if they contain > 0,1 % w/w Butadiene
489	Hydrocarbons, C4-5, if they contain > 0,1 % w/w Butadiene
490	Hydrocarbons, C2-4, C3-rich, if they contain > 0,1 % w/w Butadiene
491	Petroleum gases, liquefied, if they contain > 0,1 % w/w Butadiene
492	Petroleum gases, liquefied, sweetened, if they contain > 0,1 % w/w Butadiene
493	Gases (petroleum), C3-4, isobutane-rich, if they contain > 0,1 % w/w Butadiene
494	Distillates (petroleum), C3-6, piperylene-rich, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
495	Gases (petroleum), amine system feed, if they contain > 0,1 % w/w Butadiene
496	Gases (petroleum), benzene unit hydrodesulferised off, if they contain > 0,1 % w/w Butadiene
497	Gases (petroleum), benzene unit recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene
498	Gases (petroleum), blend oil, hydrogen-nitrogen-rich, if they contain > 0,1 % w/w Butadiene
499	Gases (petroleum), butane splitter overheads, if they contain > 0,1 % w/w Butadiene
500	Gases (petroleum), C2-3, if they contain > 0,1 % w/w Butadiene
501	Gases (petroleum), catalytic-cracked gas oil depropaniser bottoms, C4-rich acid-free, if they contain > 0,1 % w/w Butadiene
502	Gases (petroleum), catalytic-cracked naphtha debutaniser bottoms, C3-5-rich, if they contain > 0,1 % w/w Butadiene
503	Gases (petroleum), catalytic cracked naphtha depropaniser overhead, C3-rich acid-free, if they contain > 0,1 % w/w Butadiene
504	Gases (petroleum), catalytic cracker, if they contain > 0,1 % w/w Butadiene
505	Gases (petroleum), catalytic cracker, C1-5-rich, if they contain > 0,1 % w/w Butadiene
506	Gases (petroleum), catalytic polymd. naphtha stabiliser overhead, C2-4-rich, if they contain > 0,1 % w/w Butadiene
507	Gases (petroleum), catalytic reformed naphtha stripper overheads, if they contain > 0,1 % w/w Butadiene
508	Gases (petroleum), catalytic reformer C1-4-rich, if they contain > 0,1 % w/w Butadiene
509	Gases (petroleum), C6-8 catalytic reformer recycle, if they contain > 0,1 % w/w Butadiene
510	Gases (petroleum), C6-8 catalytic reformer, if they contain > 0,1 % w/w Butadiene
511	Gases (petroleum), C6-8 catalytic reformer recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene
512	Gases (petroleum), C3-5 olefinic-paraffinic alkylation feed, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
513	Gases (petroleum), C2-return stream, if they contain > 0,1 % w/w Butadiene
514	Gases (petroleum), C4-rich, if they contain > 0,1 % w/w Butadiene
515	Gases (petroleum), deethaniser overheads, if they contain > 0,1 % w/w Butadiene
516	Gases (petroleum), deisobutaniser tower overheads, if they contain > 0,1 % w/w Butadiene
517	Gases (petroleum), depropaniser dry, propene-rich (Cas No. 68477-90-7), if they contain > 0,1 % w/w Butadiene
518	Gases (petroleum), depropaniser overheads, if they contain > 0,1 % w/w Butadiene
519	Gases (petroleum), dry sour, gas-concn.-unit-off, if they contain > 0,1 % w/w Butadiene
520	Gases (petroleum), gas concn. reabsorber distn., if they contain > 0,1 % w/w Butadiene
521	Gases (petroleum), gas recovery plant depropaniser overheads, if they contain > 0,1 % w/w Butadiene
522	Gases (petroleum), Girbatol unit feed, if they contain > 0,1 % w/w Butadiene
523	Gases (petroleum), hydrogen absorber off, if they contain > 0,1 % w/w Butadiene
524	Gases (petroleum), hydrogen-rich, if they contain > 0,1 % w/w Butadiene
525	Gases (petroleum), hydrotreater blend oil recycle, hydrogen nitrogen-rich, if they contain > 0,1 % w/w Butadiene
526	Gases (petroleum), isomerised naphtha fractionator, C4-rich, hydrogen sulfide-free, if they contain > 0,1 % w/w Butadiene
527	Gases (petroleum), recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene
528	Gases (petroleum), reformer make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene
529	Gases (petroleum), reforming hydrotreater, if they contain > 0,1 % w/w Butadiene
530	Gases (petroleum), reforming hydrotreater, hydrogen-methane-rich, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
531	Gases (petroleum), reforming hydrotreater make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene
532	Gases (petroleum), thermal cracking distn., if they contain > 0,1 % w/w Butadiene
533	Tail gas (petroleum), catalytic cracked clarified oil and thermal cracked vacuum residue fractionation reflux drum, if it contains > 0,1 % w/w Butadiene
534	Tail gas (petroleum), catalytic cracked naphtha stabilisation absorber, if it contains > 0,1 % w/w Butadiene
535	Tail gas (petroleum), catalytic cracker, catalytic reformer and hydrodesulferised combined fractionater, if it contains > 0,1 % w/w Butadiene
536	Tail gas (petroleum), catalytic cracker refractionation absorber, if it contains > 0,1 % w/w Butadiene
537	Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene
538	Tail gas (petroleum), catalytic reformed naphtha separator, if it contains > 0,1 % w/w Butadiene
539	Tail gas (petroleum), catalytic reformed naphtha stabiliser, if it contains > 0,1 % w/w Butadiene
540	Tail gas (petroleum), cracked distillate hydrotreater separator, if it contains > 0,1 % w/w Butadiene
541	Tail gas (petroleum), hydrodesulfurised straight-run naphtha separator, if it contains > 0,1 % w/w Butadiene
542	Tail gas (petroleum), saturate gas plant mixed stream, C4-rich, if it contains > 0,1 % w/w Butadiene
543	Tail gas (petroleum), saturate gas recovery plant, C1-2-rich, if it contains > 0,1 % w/w Butadiene
544	Tail gas (petroleum), vacuum residues thermal cracker, if it contains > 0,1 % w/w Butadiene
545	Hydrocarbons, C3-4-rich, petroleum distillate, if they contain > 0,1 % w/w Butadiene
546	Gases (petroleum), catalytic reformed straight-run naphtha stabiliser overheads, if they contain > 0,1 % w/w Butadiene
547	Gases (petroleum), full-range straight-run naphtha dehexaniser off, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
548	Gases (petroleum), hydrocracking depropaniser off, hydrocarbon-rich, if they contain > 0,1 % w/w Butadiene
549	Gases (petroleum), light straight-run naphtha stabiliser off, if they contain > 0,1 % w/w Butadiene
550	Gases (petroleum), reformer effluent high-pressure flash drum off, if they contain > 0,1 % w/w Butadiene
551	Gases (petroleum), reformer effluent low-pressure flash drum off, if they contain > 0,1 % w/w Butadiene
552	Residues (petroleum), alkylation splitter, C4-rich, if they contain > 0,1 % w/w Butadiene
553	Hydrocarbons, C1-4, if they contain > 0,1 % w/w Butadiene
554	Hydrocarbons, C1-4, sweetened, if they contain > 0,1 % w/w Butadiene
555	Gases (petroleum), oil refinery gas distn. off, if they contain > 0,1 % w/w Butadiene
556	Hydrocarbons, C1-3, if they contain > 0,1 % w/w Butadiene
557	Hydrocarbons, C1-4, debutanizer fraction, if they contain > 0,1 % w/w Butadiene
558	Gases (petroleum), benzene unit hydrotreater depentaniser overheads, if they contain > 0,1 % w/w Butadiene
559	Gases (petroleum), C1-5, wet, if they contain > 0,1 % w/w Butadiene
560	Gases (petroleum), secondary absorber off, fluidised catalytic cracker overheads fractionator, if they contain > 0,1 % w/w Butadiene
561	Hydrocarbons, C2-4, if they contain > 0,1 % w/w Butadiene
562	Hydrocarbons, C3, if they contain > 0,1 % w/w Butadiene
563	Gases (petroleum), alkylation feed, if they contain > 0,1 % w/w Butadiene
564	Gases (petroleum), depropaniser bottoms fractionation off, if they contain > 0,1 % w/w Butadiene
565	Petroleum products, refinery gases, if they contain > 0,1 % w/w Butadiene
566	Gases (petroleum), hydrocracking low-pressure separator, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
567	Gases (petroleum), refinery blend, if they contain > 0,1 % w/w Butadiene
568	Gases (petroleum), catalytic cracking, if they contain > 0,1 % w/w Butadiene
569	Gases (petroleum), C2-4, sweetened, if they contain > 0,1 % w/w Butadiene
570	Gases (petroleum), refinery, if they contain > 0,1 % w/w Butadiene
571	Gases (petroleum), platformer products separator off, if they contain > 0,1 % w/w Butadiene
572	Gases (petroleum), hydrotreated sour kerosine dependaniser stabiliser off, if they contain > 0,1 % w/w Butadiene
573	Gases (petroleum), hydrotreated sour kerosine flash drum, if they contain > 0,1 % w/w Butadiene
574	Gases (petroleum), crude oil fractionation off, if they contain > 0,1 % w/w Butadiene
575	Gases (petroleum), dehexaniser off, if they contain > 0,1 % w/w Butadiene
576	Gases (petroleum), distillate unifiner desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene
577	Gases (petroleum), fluidised catalytic cracker fractionation off if they contain > 0,1 % w/w Butadiene
578	Gases (petroleum), fluidised catalytic cracker scrubbing secondary absorber off, if they contain > 0,1 % w/w Butadiene
579	Gases (petroleum), heavy distillate hydrotreater desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene
580	Gases (petroleum), light straight run gasoline fractionation stabiliser off, if they contain > 0,1 % w/w Butadiene
581	Gases (petroleum), naphtha unifiner desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene
582	Gases (petroleum), platformer stabiliser off, light ends fractionation, if they contain > 0,1 % w/w Butadiene
583	Gases (petroleum), preflash tower off, crude distn., if they contain > 0,1 % w/w Butadiene
584	Gases (petroleum), straight-run naphtha catalytic reforming off, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
585	Gases (petroleum), straight-run stabiliser off, if they contain > 0,1 % w/w Butadiene
586	Gases (petroleum), tar stripper off, if they contain > 0,1 % w/w Butadiene
587	Gases (petroleum), unifiner stripper off, if they contain > 0,1 % w/w Butadiene
588	Gases (petroleum), fluidised catalytic cracker splitter overheads, if they contain > 0,1 % w/w Butadiene
589	Gases (petroleum), catalytic cracked naphtha debutanizer, if they contain > 0,1 % w/w Butadiene
590	Tail gas (petroleum), catalytic cracked distillate and naphtha stabiliser, if it contains > 0,1 % w/w Butadiene
591	Tail gas (petroleum), catalytic hydrodesulfurised naphtha separator, if it contains > 0,1 % w/w Butadiene
592	Tail gas (petroleum), straight-run naphtha hydrodesulferised, if it contains > 0,1 % w/w Butadiene
593	Tail gas (petroleum), thermal-cracked distillate, gas oil and naphtha absorber, if it contains > 0,1 % w/w Butadiene
594	Tail gas (petroleum), thermal cracked hydrocarbon fractionation stabiliser, petroleum coking, if it contains > 0,1 % w/w Butadiene
595	Gases (petroleum), light steam-cracked, butadiene conc., if they contain > 0,1 % w/w Butadiene
596	Gases (petroleum), sponge absorber off, fluidised catalytic cracker and gas oil desulfuriser overhead fractionation, if they contain > 0,1 % w/w Butadiene
597	Gases (petroleum), straight-run naphtha catalytic reformer stabiliser overhead, if they contain > 0,1 % w/w Butadiene
598	Gases (petroleum), crude distn., and catalytic cracking, if they contain > 0,1 % w/w Butadiene
599	Hydrocarbons, C4, if they contain > 0,1 % w/w Butadiene
600	Alkanes, C1-4, C3-rich, if they contain > 0,1 % w/w Butadiene
601	Gases (petroleum), gas oil diethanolamine scrubber off, if they contain > 0,1 % w/w Butadiene
602	Gases (petroleum), gas oil hydrodesulfurisation effluent, if they contain > 0,1 % w/w Butadiene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
603	Gases (petroleum), gas oil hydrodesulfurisation purge, if they contain > 0,1 % w/w Butadiene
604	Gases (petroleum), hydrogenator effluent flash drum off, if they contain > 0,1 % w/w Butadiene
605	Gases (petroleum), naphtha steam cracking high-pressure residual, if they contain > 0,1 % w/w Butadiene
606	Gases (petroleum), residue visbreaking off, if they contain > 0,1 % w/w Butadiene
607	Gases (petroleum), steam-cracker C3-rich, if they contain > 0,1 % w/w Butadiene
608	Hydrocarbons, C4, steam-cracker distillate, if they contain > 0,1 % w/w Butadiene
609	Petroleum gases, liquefied, sweetened, C4 fraction, if they contain > 0,1 % w/w Butadiene
610	Hydrocarbons, C4, 1, 3-butadiene- and isobutene-free, if they contain > 0,1 % w/w Butadiene
611	Raffinates (petroleum), steam-cracked C4 fraction cuprous ammonium acetate extn., C3-5 and C3-5 unsatd., butadiene-free, if they contain > 0,1 % w/w Butadiene
612	Benzo[def]chrysene (=benzo[a]pyrene)
613	Pitch, coal tar-petroleum, if it contains > 0,005 % w/w benzo-[a]pyrene
614	Distillates (coal-petroleum), condensed-ring arom., if they contain > 0,005 % w/w benzo[a]pyrene
615	Entry deleted
616	Entry deleted
617	Creosote oil, acenaphthene fraction, acenaphthene-free, if it contains > 0,005 % w/w benzo[a]pyrene
618	Pitch, coal tar, low-temp., if it contains > 0,005 % w/w benzo[a]pyrene
619	Pitch, coal tar, low-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene
620	Pitch, coal tar, low-temp., oxidised, if it contains > 0,005 % w/w benzo[a]pyrene
621	Extract residues (coal), brown, if they contain > 0,005 % w/w benzo[a]pyrene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
622	Paraffin waxes (coal), brown-coal high-temp., tar, if they contain > 0,005 % w/w benzo[a]pyrene
623	Paraffin waxes (coal), brown-coal high-temp., tar, hydrotreated, if they contain > 0,005 % w/w benzo[a]pyrene
624	Waste solids, coal-tar pitch coking, if they contain > 0,005 w/w benzo[a]pyrene
625	Pitch, coal tar, high-temp., secondary, if it contains > 0,005 % w/w benzo[a]pyrene
626	Residues (coal), liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene
627	Coal liquids, liq. solvent extn. soln., if they contain > 0,005 % w/w benzo[a]pyrene
628	Coal liquids, liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene
629	Paraffin waxes (coal), brown-coal high-temp., tar, carbon-treated, if they contain > 0,005 % w/w benzo[a]pyrene
630	Paraffin waxes (coal), brown-coal high-temp., tar, clay-treated, if they contain > 0,005 % w/w benzo[a]pyrene
631	Paraffin waxes (coal), brown-coal high-temp., tar, silicic acid-treated, if they contain > 0,005 % w/w benzo[a]pyrene
632	Absorption oils, bicyclo arom., and heterocylic hydrocarbon fraction, if they contain > 0,005 % w/w benzo[a]pyrene
633	Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polyethylene polypropylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene
634	Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polyethylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene
635	Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polystyrene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene
636	Pitch, coal tar, high-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene
637	Dibenz[a, h]anthracene
638	Benz[a]anthracene
639	Benzo[e]pyrene
640	Benzo[j]fluoranthene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
641	Benz(e)acephenanthrylene
642	Benzo(k)fluoranthene
643	Chrysene
644	2-Bromopropane
645	Trichloroethylene
646	1, 2-Dibromo-3-chloropropane
647	2, 3-Dibromopropan-1-ol
648	1, 3-Dichloropropan-2-ol
649	*a, a, a,* -Trichlorotoluene
650	*a*-Chlorotoluene
651	1, 2-Dibromoethane
652	Hexachlorobenzene
653	Bromoethylene
654	1, 4-Dichlorobut-2-ene
655	Methyloxirane
656	(Epoxyethyl)benzene
657	1-Chloro-2, 3-epoxypropane
658	R-1-Chloro-2, 3-epoxypropane
659	1, 2-Epoxy-3-phenoxypropane
660	2, 3-Epoxypropan-1-ol
661	R-2, 3-Epoxy-1-propanol
662	2, 2'-Bioxirane
663	(2RS, 3RS)-3-(2-Chlorophenyl)-2-(4-fluorophenyl)-[1H-1, 2, 4-triazol- 1-yl)methyl]oxirane .
664	Chloromethyl methyl ether
665	2-Methoxyethanol
666	2-Ethoxyethanol
667	Oxybis[chloromethane], bis (Chloromethyl) ether
668	2-Methoxypropanol
669	Propiolactone
670	Dimethylcarbamoyl chloride
671	Urethane

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
672	2-Methoxyethyl acetate
673	2-Ethoxyethyl acetate
674	Methoxyacetic acid
675	Dibutyl phthalate
676	bis(2-Methyoxyethyl) ether
677	bis(2-Ethylhexyl) phthalate
678	bis(2-Methoxyethyl) phthalate
679	2-Methoxypropyl acetate
680	2-Ethylhexyl[[[3, 5-bis(1, 1-dimethylethyl)-4-hydroxyphenyl]-methyl]-thio] acetate
681	Acrylamide, unless regulated elsewhere in this Directive
682	Acrylonitrile
683	2-Nitropropane
684	Dinoseb, its salts and esters with the exception of those specified elsewhere in this list
685	2-Nitroanisole
686	4-Nitrobiphenyl
687	Dinitrotoluene technical grade
688	Binapacryl
690	2, 3-Dinitrotoluene
691	5-Nitroacenaphthene
692	2, 6-Dinitrotoluene
693	3, 4-Dinitrotoluene
694	3, 5-Dinitrotoluene
695	2, 5-Dinitrotoluene
696	Dinoterb, its salts and esters
697	Nitrofen
698	Dinitrotoluene
699	Diazomethane
700	1, 4, 5, 8-Tetraaminoanthraquinone (Disperse Blue 1)
701	Dimethylnitrosoamine
702	1-Methyl-3-nitro-1-nitrosoguanidine
703	Nitrosodipropylamine

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
704	2, 2'-(Nitrosoimino)bisethanol
705	4, 4'-Methylenedianiline
706	4, 4'-(4-Iminocyclohexa-2, 5-dienylidenemethylene) dianiline hydrochloride
707	4, 4'-Methylenedi-o-toluidine
708	o-Anisidine
709	3, 3'-Dimethoxybenzidine
710	Salts of o-dianisidine
711	o-Dianisidine based azo dyes
712	3, 3'-Dichlorobenzidine
713	Benzidine dihydrochloride
714	[[1, 1'-Biphenyl]-4, 4'-diyl]diammonium sulphate
715	3, 3'-Dichlorobenzidine dihydrochloride
716	Benzidine sulphate
717	Benzidine acetate
718	3, 3'-Dichlorobenzidine dihydrogen bis(sulphate)
719	3, 3'-Dichlorobenzidine sulphate
720	Benzidine based azo dyes
721	4, 4'-Bi-o-toluidine
722	4, 4'-Bi-o-toluidine dihydrochloride
723	[3, 3'-Dimethyl[1, 1'-biphenyl]-4, 4'-diyl]diammonium bis(hydrogen sulphate)
724	4, 4'-Bi-o-toluidine sulphate
725	o-Tolidine based dyes
726	Biphenyl-4-ylamine and its salts
727	Azobenzene
728	(Methyl-ONN-azoxy)methyl acetate
729	Cycloheximide
730	2-Methylaziridine
731	Imidazolidine-2-thione
732	Furan
733	Aziridine

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
734	Captafol
735	Carbadox
736	Flumioxazin
737	Tridemorph
738	Vinclozolin
739	Fluazifop-butyl
740	Flusilazole
741	1, 3, 5-Tris(oxiranylmethyl)-1, 3, 5-triazine-2, 4, 6(1H, 3H, 5H) trione
742	Thioacetamide
743	N, N-Dimethylformamide
744	Formamide
745	N-Methylacetamide
746	N-Methylformamide
747	N, N-Dimethylacetamide
748	Hexamethylphosphoric-triamide
749	Diethyl sulphate
750	Dimethyl sulphate
751	1, 3-Propanesultone
752	Dimethylsulphamoyl-chloride
753	Sulfallate
754	A mixture of: 4-[[bis-(4-fluorophenyl)methylsilyl]methyl]-4H-1, 2, 4-triazole and 1-[[bis-(4-fluorophenyl)methylsilyl]methyl]-1H-1, 2, 4-triazole (EC No. 403-250-2)
755	(+/-)-Tetrahydrofurfuryl - (R) -2-[4 -(6-chloroquinoxalin -2-yloxy) phenyloxy]propionate
756	6-Hydroxy-1-(3-Isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo) phenylazo]-1, 2-dihydro-3-pyridinecarbonitrile
757	(6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1, 3, 5-triazine-2, 4-diyl)bis[(amino-1-methylethyl)ammonium] formate
758	Trisodium [4'-(8-acetylamino-3, 6-disulfonato-2-naphthylazo)-4.-(6-benzoylamino-3-sulfonato-2-naphthylazo)-biphenyl-1, 3', 3., 1'''-tetraolato-O, O', O., O''']copper(II) (EC No. 413-590-3)

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
759	A mixture of: N-[3-Hydroxy-2-(2-methylacryloylaminomethoxy) propoxymethyl] - 2 - methylacrylamide and N-2, 3 - bis-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide and methacrylamide and 2-methyl-N-(2-methylacryloylaminomethoxymethyl)- acrylamide and N-(2,3-dihydroxypropoxymethyl)-2-methylacrylamide (EC No. 412-790-8)
760	1, 3, 5-tris-[(2S and 2R)-2, 3-Epoxypropyl]-1, 3, 5-triazine-2, 4, 6-(1H, 3H, 5H)- trione
761	Erionite
762	Asbestos
763	Petroleum
764	Distillates (petroleum), heavy hydrocracked, if they contain > 3 % w/w DMSO extract
765	Distillates (petroleum), solvent-refined heavy paraffinic, if they contain > 3 % w/w DMSO extract
766	Distillates (petroleum), solvent-refined light paraffinic, if they contain > 3 % w/w DMSO extract
767	Residual oils (petroleum), solvent deasphalted, if they contain > 3 % w/w DMSO extract
768	Distillates (petroleum), solvent-refined heavy naphthenic, if they contain > 3 % w/w DMSO extract
769	Distillates (petroleum), solvent-refined light naphthenic, if they contain > 3 % w/w DMSO extract
770	Residual oils (petroleum), solvent-refined, if they contain > 3 % w/w DMSO extract
771	Distillates (petroleum), clay-treated heavy paraffinic, if they contain > 3 % w/w DMSO extract
772	Distillates (petroleum), clay-treated light paraffinic, if they contain > 3 % w/w DMSO extract
773	Residual oils (petroleum), clay-treated, if they contain > 3 % w/w DMSO extract
774	Distillates (petroleum), clay-treated heavy naphthenic, if they contain > 3 % w/w DMSO extract
775	Distillates (petroleum), clay-treated light naphthenic, if they contain > 3 % w/w DMSO extract
776	Distillates (petroleum), hydrotreated heavy naphthenic, if they contain > 3% w/w DMSO extract

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
777	Distillates (petroleum), hydrotreated light naphthenic, if they contain > 3 % w/w DMSO extract
778	Distillates (petroleum), hydrotreated heavy paraffinic, if they contain > 3 % w/w DMSO extract
779	Distillates (petroleum), hydrotreated light paraffinic, if they contain > 3 % w/w DMSO extract
780	Distillates (petroleum), solvent-dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract
781	Residual oils (petroleum), hydrotreated, if they contain > 3 % w/w DMSO extract
782	Residual oils (petroleum), solvent-dewaxed, if they contain > 3 % w/w DMSO extract
783	Distillates (petroleum), solvent-dewaxed heavy naphthenic, if they contain > 3 % w/w DMSO extract
784	Distillates (petroleum), solvent-dewaxed light naphthenic, if they contain > 3 % w/w DMSO extract
785	Distillates (petroleum), solvent-dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract
786	Foots oil (petroleum), if it contains > 3 % w/w DMSO extract
787	Naphthenic oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract
788	Naphthenic oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract
789	Paraffin oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract
790	Paraffin oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract
791	Naphthenic oils (petroleum), complex dewaxed heavy, if they contain > 3 % w/w DMSO extract
792	Naphthenic oils (petroleum), complex dewaxed light, if they contain > 3 % w/w DMSO extract
793	Extracts (petroleum), heavy naphthenic distillate solvent, arom. conc., if they contain > 3 % w/w DMSO extract
794	Extracts (petroleum), solvent-refined heavy paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract
795	Extracts (petroleum), heavy paraffinic distillates, solvent deasphalted, if they contain > 3 % w/w DMSO extract

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
797	Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract
798	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract
799	Lubricating oils, if they contain > 3 % w/w DMSO extract
800	Distillates (petroleum), complex dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract
801	Distillates (petroleum), complex dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract
802	Distillates (petroleum), solvent dewaxed heavy paraffinic, clay-treated, if they contain > 3 % w/w DMSO extract
803	Hydrocarbons, C20-50, solvent dewaxed heavy paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract
804	Distillates (petroleum), solvent dewaxed light paraffinic,clay-treated, if they contain > 3 % w/w DMSO extract
805	Distillates (petroleum), solvent dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract
806	Extracts (petroleum), heavy naphthenic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract
807	Extracts (petroleum), heavy paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract
808	Extracts (petroleum), light paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract
809	Residual oils (petroleum), hydrotreated solvent dewaxed, if they contain > 3 % w/w DMSO extract
810	Residual oils (petroleum), catalytic dewaxed, if they contain > 3 % w/w DMSO extract
811	Distillates (petroleum), dewaxed heavy paraffinic, hydrotreated if they contain > 3 % w/w DMSO extract
812	Distillates (petroleum), dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract
813	Distillates (petroleum), hydrocracked solvent-refined, dewaxed, if they contain > 3 % w/w DMSO extract
814	Distillates (petroleum), solvent-refined light naphthenic, hydro-treated, if they contain > 3 % w/w DMSO extract
815	Extracts (petroleum), hydrotreated light paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
816	Extracts (petroleum), light naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract
817	Extracts (petroleum), light paraffinic distillate solvent, acid-treated, if they contain > 3 % w/w DMSO extract
818	Extracts (petroleum), light paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract
819	Extracts (petroleum), light vacuum gas oil solvent, hydrotreated, if they contain > 3 % w/w DMSO extract
820	Foots oil (petroleum), hydrotreated, if it contains > 3 % w/w DMSO extract
821	Lubricating oils (petroleum), C17-35, solvent-extd., dewaxed, hydrotreated, if they contain > 3 % w/w DMSO extract
822	Lubricating oils (petroleum), hydrocracked nonarom solvent-deparaffined, if they contain > 3 % w/w DMSO extract
823	Residual oils (petroleum), hydrocracked acid-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract
824	Paraffin oils (petroleum), solvent-refined dewaxed heavy, if they contain > 3 % w/w DMSO extract
825	Extracts (petroleum), heavy paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract
826	Lubricating oils (petroleum), base oils, paraffinic, if they contain > 3 % w/w DMSO extract
827	Extracts (petroleum), heavy naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract
828	Extracts (petroleum), solvent-dewaxed heavy paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract
829	Hydrocarbons, hydrocracked paraffinic distn. residues, solvent-dewaxed, if they contain > 3 % w/w DMSO extract
830	Foots oil (petroleum), acid-treated, if it contains > 3 % w/w DMSO extract
831	Foots oil (petroleum), clay-treated, if it contains > 3 % w/w DMSO extract
832	Hydrocarbons, C20-50, residual oil hydrogenation vacuum distillate, if they contain > 3 % w/w DMSO extract
833	Distillates (petroleum), solvent-refined hydrotreated heavy, hydrogenated, if they contain > 3 % w/w DMSO extract

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
834	Distillates (petroleum), solvent-refined hydrocracked light, if they contain > 3 % w/w DMSO extract
835	Lubricating oils (petroleum), C18-40, solvent-dewaxed hydrocracked distillate-based, if they contain > 3 % w/w DMSO extract
836	Lubricating oils (petroleum), C18-40, solvent-dewaxed hydrogenated raffinate-based, if they contain > 3 % w/w DMSO extract
837	Hydrocarbons, C13-30, arom.-rich, solvent-extd., naphthenic distillate, if they contain > 3 % w/w DMSO extract
838	Hydrocarbons, C16-32, arom. rich, solvent-extd., naphthenic distillate, if they contain > 3 % w/w DMSO extract
839	Hydrocarbons, C37-68, dewaxed deasphalted hydrotreated vacuum distn. residues, if they contain > 3 % w/w DMSO extract
840	Hydrocarbons, C37-65, hydrotreated deasphalted vacuum distn. residues, if they contain > 3 % w/w DMSO extract
841	Distillates (petroleum), hydrocracked solvent-refined light, if they contain > 3 % w/w DMSO extract
842	Distillates (petroleum), solvent-refined hydrogenated heavy, if they contain > 3 % w/w DMSO extract
843	Lubricating oils (petroleum), C18-27, hydrocracked solvent-dewaxed, if they contain > 3 % w/w DMSO extract
844	Hydrocarbons, C17-30, hydrotreated solvent-deasphalted atm. distn. residue, distn. lights, if they contain > 3 % w/w DMSO extract
845	Hydrocarbons, C17-40, hydrotreated solvent-deasphalted distn. residue, vacuum distn. lights, if they contain > 3 % w/w DMSO extract
846	Hydrocarbons, C13-27, solvent-extd., light naphthenic, if they contain > 3 % w/w DMSO extract
847	Hydrocarbons, C14-29, solvent-extd., light naphthenic, if they contain > 3 % w/w DMSO extract
848	Foots oil (petroleum), carbon-treated, if it contains > 3 % w/w DMSO extract
849	Foots oil (petroleum), silicic acid-treated, if it contains > 3 % w/w DMSO extract
850	Hydrocarbons, C27-42, dearomatised, if they contain > 3 % w/w DMSO extract

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
851	Hydrocarbons, C17-30, hydrotreated distillates, distn. lights, if they contain > 3 % w/w DMSO extract
852	Hydrocarbons, C27-45, naphthenic vacuum distn., if they contain > 3 % w/w DMSO extract
853	Hydrocarbons, C27-45, dearomatised, if they contain > 3 % w/w DMSO extract
854	Hydrocarbons, C20-58, hydrotreated, if they contain > 3 % w/w DMSO extract
855	Hydrocarbons, C27-42, naphthenic, if they contain > 3 % w/w DMSO extract
856	Extracts (petroleum), light paraffinic distillate solvent, carbon-treated, if they contain > 3 % w/w DMSO extract
857	Extracts (petroleum), light paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract
858	Extracts (petroleum), light vacuum, gas oil solvent, carbon-treated, if they contain > 3 % w/w DMSO extract
859	Extracts (petroleum), light vacuum gas oil solvent, clay-treated, if they contain > 3 % w/w DMSO extract
860	Residual oils (petroleum), carbon-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract
861	Residual oils (petroleum), clay-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract
862	Lubricating oils (petroleum), C>25, solvent-extd., deasphalted, dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract
863	Lubricating oils (petroleum), C17-32, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract
864	Lubricating oils (petroleum), C20-35, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract
865	Lubricating oils (petroleum), C24-50, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract
866	Distillates (petroleum), sweetened middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
867	Gas oils (petroleum), solvent-refined, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
868	Distillates (petroleum), solvent-refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
869	Gas oils (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
870	Distillates (petroleum), acid-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
871	Distillates (petroleum), acid-treated light, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
872	Gas oils (petroleum), chemically neutralised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
873	Distillates (petroleum), chemically neutralised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
874	Distillates (petroleum), clay-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
875	Distillates (petroleum), hydrotreated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
876	Gas oils (petroleum), hydrodesulfurised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
877	Distillates (petroleum), hydrodesulfurised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
878	Distillates (petroleum), catalytic reformer fractionator residue, high-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
879	Distillates (petroleum), catalytic reformer fractionator residue, intermediate-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
880	Distillates (petroleum), catalytic reformer fractionator residue, low-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
881	Alkanes, C12-26-branched and linear, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
882	Distillates (petroleum), highly refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
883	Distillates (petroleum), catalytic reformer, heavy arom., conc., except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
884	Gas oils, paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
885	Naphtha (petroleum), solvent-refined hydrodesulfurised heavy, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
886	Hydrocarbons, C16-20, hydrotreated middle distillate, distn. lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
887	Hydrocarbons, C12-20, hydrotreated paraffinic, distn. lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
888	Hydrocarbons, C11-17, solvent-extd., light naphthenic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
889	Gas oils, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
890	Distillates (petroleum), carbon-treated light paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
891	Distillates (petroleum), intermediate paraffinic, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
892	Distillates (petroleum), intermediate paraffinic, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
893	Lubricating greases, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
894	Slack wax (petroleum), except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
895	Slack wax (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
896	Slack wax (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
897	Slack wax (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
898	Slack wax (petroleum), low-melting, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
899	Slack wax (petroleum), low-melting, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
900	Slack wax (petroleum), low-melting, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
901	Slack wax (petroleum), low-melting, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
902	Slack wax (petroleum), low-melting, silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
903	Slack wax (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
904	Petrolatum, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
905	Petrolatum (petroleum), oxidised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
906	Petrolatum (petroleum), alumina-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
907	Petrolatum (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
908	Petrolatum (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
909	Petrolatum (petroleum), silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
910	Petrolatum (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
911	Distillates (petroleum), light catalytic cracked
912	Distillates (petroleum), intermediate catalytic cracked
913	Distillates (petroleum), light thermal cracked
914	Distillates (petroleum), hydrodesulfurised light catalytic cracked
915	Distillates (petroleum), light steam-cracked naphtha
916	Distillates (petroleum), cracked steam-cracked petroleum distillates
917	Gas oils (petroleum), steam-cracked
918	Distillates (petroleum), hydrodesulfurised thermal cracked middle
919	Gas oils (petroleum), thermal-cracked, hydrodesulfurised
920	Residues (petroleum), hydrogenated steam-cracked naphtha
921	Residues (petroleum), steam-cracked naphtha distn.
922	Distillates (petroleum), light catalytic cracked, thermally degraded
923	Residues (petroleum), steam-cracked heat-soaked naphtha
924	Gas oils (petroleum), light vacuum, thermal-cracked hydrodesulfurised
925	Distillates (petroleum), hydrodesulfurised middle coker
926	Distillates (petroleum), heavy steam-cracked
927	Residues (petroleum), atm. Tower

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
928	Gas oils (petroleum), heavy vacuum
929	Distillates (petroleum), heavy catalytic cracked
930	Clarified oils (petroleum), catalytic cracked
931	Residues (petroleum), catalytic reformer fractionator
932	Residues (petroleum), hydrocracked
933	Residues (petroleum), thermal cracked
934	Distillates (petroleum), heavy thermal cracked
935	Gas oils (petroleum), hydrotreated vacuum
936	Residues (petroleum), hydrodesulfurised atmospheric tower
937	Gas oils (petroleum), hydrodesulfurised heavy vacuum
938	Residues (petroleum), steam-cracked
939	Residues (petroleum), atmospheric
940	Clarified oils (petroleum), hydrodesulfurised catalytic cracked
941	Distillates (petroleum), hydrodesulfurised intermediate catalytic cracked
942	Distillates (petroleum), hydrodesulfurised heavy catalytic cracked
943	Fuel oil, residues-straight-run gas oils, high-sulfur
944	Fuel oil, residual
945	Residues (petroleum), catalytic reformer fractionator residue distn.
946	Residues (petroleum), heavy coker gas oil and vacuum gas oil
947	Residues (petroleum), heavy coker and light vacuum
948	Residues (petroleum), light vacuum
949	Residues (petroleum), steam-cracked light
950	Fuel oil, No. 6
951	Residues (petroleum), topping plant, low-sulfur
952	Gas oils (petroleum), heavy atmospheric
953	Residues (petroleum), coker scrubber, condensed-ring-arom.,-contg.
954	Distillates (petroleum), petroleum residues vacuum
955	Residues (petroleum), steam-cracked, resinous
956	Distillates (petroleum), intermediate vacuum
957	Distillates (petroleum), light vacuum
958	Distillates (petroleum), vacuum
959	Gas oils (petroleum), hydrodesulfurised coker heavy vacuum

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
960	Residues (petroleum), steam-cracked, distillates
961	Residues (petroleum), vacuum, light
962	Fuel oil, heavy, high-sulfur
963	Residues (petroleum), catalytic cracking
964	Distillates (petroleum), intermediate catalytic cracked, thermally degraded
965	Residual oils (petroleum)
966	Residues, steam cracked, thermally treated
967	Distillates (petroleum), hydrodesulfurised full-range middle
968	Distillates (petroleum), light paraffinic
969	Distillates (petroleum), heavy paraffinic
970	Distillates (petroleum), light naphthenic
971	Distillates (petroleum), heavy naphthenic
972	Distillates (petroleum), acid-treated heavy naphthenic
973	Distillates (petroleum), acid-treated light naphthenic
974	Distillates (petroleum), acid-treated heavy paraffinic
975	Distillates (petroleum), acid-treated light paraffinic
976	Distillates (petroleum), chemically neutralised heavy paraffinic
977	Distillates (petroleum), chemically neutralised light paraffinic
978	Distillates (petroleum), chemically neutralised heavy naphthenic
979	Distillates (petroleum), chemically neutralised light naphthenic
980	Extracts (petroleum), light naphthenic distillate solvent
981	Extracts (petroleum), heavy paraffinic distillate solvent
982	Extracts (petroleum), light paraffinic distillate solvent
983	Extracts (petroleum), heavy naphthenic distillate solvent
984	Extracts (petroleum), light vacuum gas oil solvent
985	Hydrocarbons, C26-55, arom. rich
986	Disodium 3, 3'-[[1, 1'-biphenyl]-4, 4'-diylbis(azo)] bis(4-aminonaphthalene-1-sulphonate)
987	Disodium 4-amino-3-[[4'-[(2, 4-diaminophenyl)azo] [1,1'-biphenyl]-4-yl] azo]-5-hydroxy-6-(phenylazo)naphthalene-2, 7-disulphonate
988	Tetrasodium 3, 3'-[[1,1'-biphenyl]-4, 4'-diylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2, 7-disulphonate]

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
989	4-o-Tolylazo-o-toluidine
990	4-Aminoazobenzene
991	Disodium[5-[[4'-[[2, 6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)-azo]phenyl]azo][1, 1'-biphenyl]-4-yl]azo]salicylato(4-)]cuprate(2-)
992	Resorcinol diglycidyl ether
993	1, 3-Diphenylguanidine
994	Heptachlor-epoxide
995	4-Nitrosophenol
996	Carbendazim
997	Allyl glycidyl ether
998	Chloroacetaldehyde
999	Hexane
1000	2-(2-Methoxyethoxy)ethanol
1001	(+/-)-2-(2, 4-Dichlorophenyl)-3-(1H-1, 2, 4-triazol-1-yl)propyl-1, 1, 2, 2-tetrafluoroethylether
1002	4-[4-(1, 3-Dihydroxyprop-2-yl) phenylamino]-1, 8-dihydroxy-5-nitroanthraquinone
1003	5, 6, 12, 13-Tetrachloroanthra(2, 1, 9-def:6, 5, 10-d'e'f')diisoquinoline-1, 3, 8, 10 (*2H, 9H*)-tetrone
1004	Tris(2-Chloroethyl) phosphate
1005	4'-Ethoxy-2-benzimidazoleanilide
1006	Nickel dihydroxide
1007	N, N-Dimethylaniline
1008	Simazine
1009	Bis(cyclopentadienyl)-bis(2, 6-difluoro-3-(pyrrol-1-yl)-phenyl) titanium
1010	N, N, N', N'-Tetraglycidyl-4, 4'-diamino-3, 3'-diethyldiphenylmethane
1011	Divanadium pentaoxide
1012	Alkali salts of pentachlorophenol
1013	Phosphamidon
1014	N-(Trichloromethylthio)phthalimide
1015	N-2-Naphthylaniline
1016	Ziram

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1017	1-Bromo-3, 4, 5-trifluorobenzene
1018	Propazine
1019	3-(4-Chlorophenyl)-1, 1-dimethyluronium trichloroacetate; monuron-TCA
1020	Isoxaflutole
1021	Kresoxim-methyl
1022	Chlordecone
1023	9-Vinylcarbazole
1024	2-Ethylhexanoic acid
1025	Monuron
1026	Morpholine-4-carbonyl chloride
1027	Daminozide
1028	Alachlor
1029	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine
1030	Ioxynil
1031	3, 5-Dibromo-4-hydroxybenzonitrile
1032	2, 6-Dibromo-4-cyanophenyl octanoate
1033	[4-[[4-(Dimethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)-amino]phenyl]methylene]cyclohexa-2, 5-dien-1-ylidene] (ethyl) (3-sulphonatobenzyl)ammonium, sodium salt
1034	5-Chloro-1, 3-dihydro-2H-indol-2-one
1035	Benomyl
1036	Chlorothalonil
1037	N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidinemonohydrochloride
1038	4, 4'-Methylenebis(2-ethylaniline)
1039	Valinamide
1040	[(p-Tolyloxy)methyl]oxirane
1041	[(m-Tolyloxy)methyl]oxirane
1042	2, 3-Epoxypropyl o-tolyl ether
1043	[(Tolyloxy)methyl]oxirane, cresyl glycidyl ether
1044	Di-allate

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1045	Benzyl 2, 4-dibromobutanoate
1046	Trifluoroiodomethane
1047	Thiophanate-methyl
1048	Dodecachloropentacyclo[5.2.1.02, 6.03, 9.05, 8]decane
1049	Propyzamide
1050	Butyl glycidyl ether
1051	2, 3, 4-Trichlorobut-1-ene
1052	Chinomethionate
1053	(R)-a-Phenylethylammonium (-)-(1R, 2S)-(1, 2-epoxypropyl) phosphonate monohydrate
1054	5-Ethoxy-3-trichloromethyl-1, 2, 4-thiadiazole
1055	Disperse Yellow 3
1056	1, 2, 4-Triazole
1057	Aldrin
1058	Diuron
1059	Linuron
1060	Nickel carbonate
1061	3-(4-Isopropylphenyl)-1, 1-dimethylurea
1062	Iprodione
1063	4-Cyano-2, 6-diiodophenyl octanoate
1064	5-(2, 4-Dioxo-1, 2, 3, 4-tetrahydropyrimidine)-3-fluro-2-hydroxymethylterahydrofuran
1065	Crotonaldehyde
1066	Hexahydrocyclopenta(c)pyrrole-1-(1H)-ammonium N-ethoxy-carbonyl-N-(p-olylsulfonyl)azanide
1067	4, 4'-Carbonimidoylbis[N,N-dimethylaniline]
1068	DNOC
1069	Toluidinium chloride
1070	Toluidine sulphate (1:1)
1071	2-(4-tert-Butylphenyl)ethanol
1072	Fenthion
1073	Chlordane, pur
1074	Hexan-2-one

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1075	Fenarimol
1076	Acetamide
1077	N-cyclohexyl-N-methoxy-2, 5-dimethyl-3-furamide
1078	Dieldrin
1079	4, 4'- Isobutylethylidenediphenol
1080	Chlordimeform
1081	Amitrole
1082	Carbaryl
1083	Distillates (petroleum), light hydrocracked
1084	1-Ethyl-1-methylmorpholinium bromide
1085	(3-Chlorophenyl)-(4-methoxy-3-nitrophenyl)methanone
1086	Fuels, diesel, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen
1087	Fuel oil, No. 2
1088	Fuel oil, No. 4
1089	Fuels, diesel, No. 2
1090	2, 2-Dibromo-2-nitroethanol
1091	1-Ethyl-1-methylpyrrolidinium bromide
1092	Monocrotophos
1093	Nickel
1094	Bromomethane
1095	Chloromethane
1096	Iodomethane
1097	Bromoethane
1098	Heptachlor
1099	Fentin hydroxide
1100	Nickel sulphate
1101	3, 5, 5-Trimethylcyclohex-2-enone
1102	2, 3-Dichloropropene
1103	Fluazifop-P-butyl
1104	(S)-2, 3-Dihydro-1H-indole-carboxylic acid
1105	Toxaphene

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1106	(4-Hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride
1107	CI Solvent yellow 14
1108	Chlozolinate
1109	Alkanes, C10-13, chloro
1110	Pentachlorophenol
1111	2, 4, 6-Trichlorophenol
1112	Diethylcarbamoyl-chloride
1113	1-Vinyl-2-pyrrolidone
1114	Myclobutanil; 2-(4-chlorophenyl)-2-(1H-1, 2, 4-triazol-1-ylmethyl)-hexanenitrile
1115	Fentin acetate
1116	Biphenyl-2-ylamine
1117	Trans-4-cyclohexyl-L-proline monohydro-chloride
1118	2-Methyl-m-phenylene diisocyanate
1119	4-Methyl-m-phenylene diisocyanate
1120	m-Tolylidene diisocyanate
1121	Fuels, jet aircraft, coal solvent extn., hydrocracked hydrogenated
1122	Fuels, diesel, coal solvent extn., hydrocracked hydrogenated
1123	Pitch, if it contains > 0,005 % w/w benzo[a]pyrene
1124	2-Butanone oxime
1125	Hydrocarbons, C16-20, solvent-dewaxed hydrocracked paraffinic distn. residue
1126	a, a-Dichlorotoluene
1127	Mineral wool, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na2O + K2O + CaO + MgO + BaO) content greater than 18 % by weight]
1128	Reaction product of acetophenone, formaldehyde, cyclohexylamine, methanol and acetic acid
1129	Salts of 4, 4'-carbonimidoylbis[N, N-dimethylaniline]
1130	1, 2, 3, 4, 5, 6-Hexachlorcyclohexanes with the exception of those specified elsewhere in this Part
1131	Trisodium bis(7-acetamido-2-(4-nitro-2-oxidophenylazo)-3-sulfonato-1-naphtholato)chromate(1-)

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1132	A mixture of: 4-allyl-2, 6-bis(2, 3-epoxypropyl)phenol, 4-allyl-6-(3-(6-(3-(6-(3-(4-allyl-2, 6-bis(2,3-epoxypropyl)-phenoxy)2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-4-allyl-2-(2, 3-epoxypropyl)-phenoxy-2-hydroxypropyl-2-(2, 3-epoxypropyl)-phenol, 4-allyl-6-(3-(4-allyl-2, 6-bis(2, 3-epoxypropyl)phenoxy)-2-hydroxypropyl)-2-(2, 3-epoxypropyl)phenoxy)phenol and 4-allyl-6-(3-(6-(3-(4-allyl-2, 6-bis (2, 3-epoxypropyl)-phenoxy)-2-hydroxypropyl)-4-allyl-2-(2, 3-epoxypropyl) phenoxy)2-hydroxypropyl)-2-(2, 3-epoxypropyl)phenol
1133	Costus root oil (*Saussurea lappa* Clarke), when used as a fragrance ingredient
1134	7-Ethoxy-4-methylcoumarin, when used as a fragrance ingredient
1135	Hexahydrocoumarin, when used as a fragrance ingredient
1136	Peru balsam (INCI name: *Myroxylon pereirae*, when used as a fragrance ingredient'
1137	Isobutyl nitrite
1138	Isoprene (stabilized) (2-methyl-1, 3-butadiene)
1139	1-bromopropane n-propyl bromide
1140	chloroprene (stabilized) (2-chlorobuta-1, 3-diene)
1141	1, 2, 3-trichloropropane
1142	Ethylene glycol dimethyl ether (EGDME)
1143	Dinocap (ISO)
1144	Diaminotoluene, technical product -mixture of [4-methyl-m-phenylene diamine][1] and [2-methyl-m-phenylene diamine][2] methylphenylenediamine
1145	p-chlorobenzotrichloride
1146	Diphenylether; octabromo derivate
1147	1,2-bis(2-methoxyethoxy)ethane triethylene glycol dimethyl ether (TEGDME)
1148	Tetrahydrothiopyran-3-carboxaldehyde
1149	4, 4'-bis(dimethylamino)benzophenone (Michler's ketone)
1150	Oxiranemethanol, 4-methylbenzene-sulfonate, (S)
1151	1, 2-benzenedicarboxylic acid, dipentylester, branched and linear [1] n-pentyl-isopentylphthalate [2] di-n-pentyl phthalate [3] diisopentylphthalate [4]
1152	Benzyl butyl phthalate (BBP)

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1153	1,2-benzenedicarboxylic acid di-C 7-11, branched and linear alkylesters
1154	A mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl) pyrazol-4-yl) penta-2, 4-dienyli-dene)-4, 5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate and trisodium 4-(3-ethoxycarbonyl-4-(5-(3ethoxycarbonyl-5-oxido-1-(4-sulfonato-phenyl)pyrazol-4-yl) penta-2, 4-dienylidene)-4, 5-dihydro-5-oxopy-razol-1yl)benzenesulfonate
1155	(methylenebis(4,1-phenylenazo(1-(3-(dimethylamino) propyl)-1, 2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5, 3diyl))}-1, 1'-dipyridinium dichloride dihydrochloride
1156	2-[2-hydroxy-3-(2-chlorophenyl) carbamoyl-1-naphthylazo]7-[2-hydroxy-3-(3-methylphenyl)-2-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl) carbamoyl-1-naphthylazo]fluoren-9-one
1157	azafenidin
1158	2, 4, 5-trimethylaniline [1] 2, 4, 5-trimethylaniline hydrochloride [2]
1159	4, 4'-thiodianiline and its salts
1160	4, 4'-oxydianiline (p-aminophenyl ether) and its salts
1161	N, N, N', N'-tetramethyl-4, 4'-methylendianiline
1162	6-methoxy-m-toluidine (p-cresidine)
1163	3-ethyl-2-methyl-2-(3-methylbutyl)-1, 3-oxazolidine
1164	A mixture of: 1, 3, 5-tris(3-aminomethylphenyl)-1, 3, 5(1H,3H,5H)-triazine-2, 4, 6-trione and a mixture of oligomers of 3, 5-bis(3-aminomethylphenyl)-1-poly[3, 5-bis(3-aminomethylphenyl)-2, 4, 6-trioxo-1, 3, 5-(1H, 3H, 5H)-triazin-1-yl]1, 3, 5-(1H,3H,5H)-triazine-2, 4, 6-trione
1165	2-nitrotoluene
1166	tributyl phosphate
1167	naphthalene
1168	nonylphenol [1] 4-nonylphenol, branched [2]
1169	1, 1, 2-trichloroethane
1170	pentachloroethane
1171	vinylidene chloride (1, 1-dichloroethylene)
1172	allyl chloride (3-chloropropene)
1173	1, 4-dichlorobenzene (p-dichlorobenzene)

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1174	bis(2-chloroethyl) ether
1175	phenol and it's alkali salts
1176	bisphenol A (4, 4'-isopropylidenediphenol)
1177	trioxymethylene (1, 3, 5-trioxan)
1178	propargite (ISO)
1179	1-chloro-4-nitrobenzene
1180	molinate (ISO)
1181	fenpropimorph
1182	Epoxiconazole
1183	methyl isocyanate
1184	N, N-dimethylanilinium tetrakis(pentafluorophenyl)borate
1185	O, O'-(ethenylmethylsilylene) di[(4-methylpentan-2-one) oxime]
1186	A 2:1 mixture of: 4-(7-hydroxy-2, 4, 4-trimethyl-2-chromanyl) resorcinol-4-yl-tris(6-diazo-5, 6-dihydro-5-oxonaphthalen-1sulfonate) and 4-(7-hydroxy-2, 4, 4-trimethyl-2-chromanyl) resorcinol bis (6-diazo-5, 6-dihydro-5-oxonaphthalen-1-sulfonate)
1187	a mixture of: reaction product of 4, 4-methylenebis[2-(4-hydroxy-benzyl)-3, 6-dimethylphenol] and 6-diazo-5, 6-dihydro-5-oxo-naphthalenesulfonate (1:2) and reaction product of 4, 4-methylenebis[2-(4-hydroxybenzyl)-3, 6-dimethylphenol] and 6-diazo-5, 6-dihydro-5-oxonaphthalenesulfonate (1:3)
1188	Malachite green hydrochloride [1] malachite green oxalate [2]
1189	1-(4-chlorophenyl)-4, 4-dimethyl-3-(1, 2, 4-triazol-1-ylmethyl) pentan-3-ol
1190	5-(3-butyryl-2, 4, 6-trimethylphenyl)-2-[1-(ethoxyimino) propyl]- 3-hydroxycyclohex-2-en-1-one
1191	trans-4-phenyl-L-proline
1192	bromoxynil heptanoate (ISO)
1193	A mixture of: 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2, 5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo] benzoic acid and 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2naphthyl) azo]-2, 5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl) azo]benzoic acid
1194	2-{4-(2-ammoniopropylamino)-6-[4-hydroxy-3-(5-methyl-2methoxy-4-sulfamoylphenylazo)-2-sulfonatonaphth-7ylamino]-1, 3, 5-triazin-2-ylamino}-2-aminopropyl formate

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1195	5-nitro-o-toluidine [1] 5-nitro-o-toluidine hydrochloride [2]
1196	1-(1-naphthylmethyl)quinolinium
1197	(R)-5-bromo-3-(1-methyl-2-pyrrolidinyl methyl)-1H-indole
1198	pymetrozine (ISO)
1199	oxadiargyl (ISO)
1200	chlorotoluron (3-(3-chloro-p-tolyl)-1,1-dimethylurea)
1201	N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl] acetamide
1202	1, 3-bis(vinylsulfonylacetamido)-propane
1203	p-phenetidine (4-ethoxyaniline)
1204	m-phenylenediamine and its salts
1205	residues (coal tar), creosote oil distn., if it contains > 0,005 % w/w benzo[a]pyrene
1206	creosote oil, acenaphthene fraction, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene
1207	creosote oil, if it contains > 0,005 % w/w benzo[a]pyrene
1208	creosote, if it contains > 0,005 % w/w benzo[a]pyrene
1209	creosote oil, high-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene
1210	extract residues (coal), creosote oil acid, wash oil extract residue, if it contains > 0,005 % w/w benzo[a]pyrene
1211	creosote oil, low-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene
1212	6-Methoxy-2, 3-Pyridinediamine and its HCl salt, when used as a substance in hair dye products
1213	2, 3-Naphthalenediol, when used as a substance in hair dye products
1214	2, 4-Diaminodiphenylamine, when used as a substance in hair dye products
1215	2, 6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a substance in hair dye products
1216	2-Methoxymethyl-p-Aminophenol and its HCl salt, when used as a substance in hair dye products
1217	4, 5-Diamino-1-Methylpyrazole and its HCl salt, when used as a substance in hair dye products

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1218	4, 5-Diamino-1-[(4-Chlorophenyl)Methyl]-1H-Pyrazole Sulfate, when used as a substance in hair dye products
1219	4-Chloro-2-Aminophenol, when used as a substance in hair dye products
1220	4-Hydroxyindole, when used as a substance in hair dye products
1221	4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a substance in hair dye products
1222	5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a substance in hair dye products
1223	N, N-Diethyl-m-Aminophenol, when used as a substance in hair dye products
1224	N, N-Dimethyl-2, 6-Pyridinediamine and its HCl salt, when used as a substance in hair dye products
1225	N-Cyclopentyl-m-Aminophenol, when used as a substance in hair dye products
1226	N-(2-Methoxyethyl)-p-phenylenediamine and its HCl salt, when used as a substance in hair dye products
1227	2, 4-Diamino-5-methylphenetol and its HCl salt, when used as a substance in hair dye products
1228	1, 7-Naphthalenediol, when used as a substance in hair dye products
1229	3, 4-Diaminobenzoic acid, when used as a substance in hair dye products
1230	2-Aminomethyl-p-aminophenol and its HCl salt, when used as a substance in hair dye products
1231	Solvent Red 1 (CI 12150), when used as a substance in hair dye products
1232	Acid Orange 24 (CI 20170), when used as a substance in hair dye products
1233	Acid Red 73 (CI 27290), when used as a substance in hair dye products
1234	PEG-3, 2', 2'-di-p-Phenylenediamine
1235	6-Nitro-o-Toluidine
1236	HC Yellow No. 11
1237	HC Orange No. 3
1238	HC Green No. 1

FIRST SCHEDULE — *(continued)*

Ref. No.	Substance
1239	HC Red No. 8 and its salts
1240	Tetrahydro-6-nitroquinoxaline and its salts
1241	Disperse Red 15, except as impurity in Disperse Violet 1
1242	4-amino-3-fluorophenol
1243	N, N'-dihexadecyl-N, N'-bis(2-hydroxyethyl)propanediamide Bishydroxyethyl Biscetyl Malonamide

(1) for the individual ingredient see reference number 364.

(2) for the individual ingredient see reference number 413.

Part II (Regulation 7(2))

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

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1a	Boric acid, borates and tetraborates with the exception of substance No. 1184 in Part I	(a) Talc (b) Products for oral hygiene (c) Other products (excluding bath products and hair waving products)	(a) 5% (by mass/mass as boric acid) (b) 0.1% (by mass/mass as boric acid) (c) 3% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid) (b) Not to be used in products for children under 3 years of age (c) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin	(a) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin (b) 1. Not to be swallowed 2. Not to be used for children under 3 years of age (c) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
				2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)	
1b	Tetraborates	(a) Bath products (b) Hair waving products	(a) 18% (by mass/mass as boric acid) (b) 8% (by mass/mass as boric acid)	(a) Not to be used in products for children under 3 years of age	(a) Not to be used for bathing children under 3 years of age (b) Rinse well
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products: - General use - Professional use (b) Depilatories	- 8% ready for use pH 7-9.5 - 11% ready for use pH 7-9.5 - 5% ready for use pH 7-2.7 - 2% ready for use pH 7-9.5	(a)(b)(c) The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: - Avoid contact with eyes	(a) - Contains thioglycolate - Follow the instructions - Keep out of reach of children - For professional use only

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
		(c) Other hair care products which are removed after application	Percentages calculated as thioglycollic acid	- In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice - Wear suitable gloves (a) and (c) only	(b) and (c) - Contains thioglycolate - Follow the instruction - Keep out of reach of children
2b	Thioglycolic acid esters	(a) Hair waving or straightening products: - General use - Professional use	- 8% ready for use pH 6-9.5 - 11% ready for use pH 6-9.5 Percentages calculated as thioglycollic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: ■ May cause sensitisation in the event of skin contact ■ Avoid contact with eyes ■ In the event of contact with eyes, rinse off with plenty of water and seek medical advice ■ Wear suitable gloves	- Contains thioglycollate - Follow the instructions - Keep out of reach of children - For professional use only
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		- For professional use only

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
4	Ammonia		6% calculated as NH_3		- Above 2%: contains ammonia
5	Tosylchloramide sodium		0.2%		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%		
8	p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine ([5]), with exception of those derivatives listed elsewhere in this Part	Oxidizing colouring agents for hair dyeing (a) General use (b) Professional use	6% calculated as free base		(a) - Can cause an allergic reaction - Contains phenylenediamines - Do not use to dye eyelashes or eyebrows (b) - For professional use only - Contains phenylenediamines - Can cause an allergic reaction. - Wear suitable gloves
9	Methylphenyle nediamines, their N-	Oxidizing colouring agents for hair dyeing	10% calculated as free base		(a) Can cause an allergic reaction

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
	substituted derivatives and their salts 1([1]) with the exception of substance N°364 and 413 in Part I	(a) General use (b) Professional use			- Contains Phenylenediamines - Do not use to dye eyelashes or eyebrows (b) For professional use only - Contains phenylenediamines - Can cause an allergic reaction - Wear suitable gloves
10	Diaminophenols([1])	Oxidizing colouring agents for hair dyeing (a) General use (b) Professional use	10% calculated as free base		(a) - Can cause an allergic reaction - Contains diaminophenols - Do not use to dye eyelashes or eyebrows (b) For professional use only - Contains diaminophenols - Can cause an allergic reaction - Wear suitable gloves

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
11	Dichloro-phen		0.5%		- Contains dichlorophen
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% H_2O_2 (40 volumes) present or released (b) 4% of H_2O_2 present or released (c) 2% of H_2O_2 present or released (d) 0.1% of H_2O_2 present or released		(a) (b) (c) - Contains hydrogen peroxide - Avoid contact with eyes - Rinse eyes immediately if product comes into contact with them (a) Wear suitable gloves
13	Formal-dehyde	Nail hardeners	5% calculated as formal-dehyde		Protect cuticles with grease or oil Contains for-maldehyde ([2])
14	Hydroqui-none (3)	(a) Oxidizing colouring agent for hair-dyeing 1. General use 2. Professio-nal use	(a) 0.3% (b) 0.02% after mixing for use	Professional use only	(a) 1. Do not use to dye eyelashes or eyebrows - Rinse the eyes imme-diately if the product comes into contact with them

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
		(b) Artificial nail systems			- Contains hydro-quinone 2. For profes-sional use only Contains hydroquinone - Rinse the eyes imme-diately if the product comes into contact with them (b) - For profes-sional use only - Avoid skin contact - Read directions for use carefully
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent (b) Hair straighte-ner 1. General use 2. Professio-nal use	(a) 5% by weight (4) (b) 1. 2% by weight (4) 2. 4.5% by weight (4) (c) up to pH 12.7		(a) - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
		(c) pH adjuster - depilatories (d) Other uses as pH adjuster	(d) up to pH 11		(b) 1. - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children 2. - For professional use only - Avoid contact with eyes - Can cause blindness (c) - Keep out of reach of children - Avoid contact with eyes
15b	Lithium hydroxide	(a) Hair straightener 1. General use 2. Professional use (b) pH adjuster - for depilatories	(a) 1. 2% by weight [6] 2. 4.5% by weight [6]	(b) pH value not to exceed pH 12, 7 (c) pH value not to exceed pH 11	(a) 1. - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
		(c) Other uses - as pH adjuster (for rinse-off products only)			2. - For professional use only - Avoid contact with eyes - Can cause blindness
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) pH adjuster - for depilatories (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7% by weight calcium hydroxide	(b) pH value not to exceed pH 12.7 (c) pH value not to exceed pH 11	(a) - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children (b) - Contains alkali - Keep out of reach of children - Avoid contact with eyes
16	1-Naphthol and its salts	Oxidizing colouring agents for hair dyeing	2%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	- Can cause allergic reaction
17	Sodium nitrite	Rust inhibitor	0.2%	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
18	Nitrome-thane	Rust inhibitor	0.3%		
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base		
22	Resorcinol (3)	(a) Oxidizing colouring agent for hair dyeing 1. General use 2. Professio-nal use (b) Hair lotions and shampoos	(a) 5% (b) 0.5%		(a) 1. - Contains resorcinol - Rinse hair well after application - Do not use to dye eyelashes or eyebrows - Rinse eyes immediately if product comes into contact with them 2. - For professional use only - Contains resorcinol - Rinse eyes immediately if product comes into contact with them (b) - Contains resorcinol

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2% calculated as sulphur pH up to 12.7 (b) 6% calculated as sulphur pH up to 12.7		(a) - Keep out of reach of children - Avoid contact with eyes (b) - Keep out of reach of children - Avoid contact with eyes
24	Water-soluble zinc salts with the exception of zinc-4-hydroxy-benzene-sulphonate and zinc pyrithione		1% calculated as zinc		
25	Zinc 4-hydroxy-benzene sulphonate	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		- Avoid contact with eyes
26	Ammonium monofluoro phosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%	**Thailand only** 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%	- Contains ammonium monofluoro-phosphate

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
27	Sodium monofluoro-phosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium monofluoro-phosophate
28	Potassium monofluoro-phosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium monofluoro-phosphate
29	Calcium monofluoro-phosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains calcium monofluoro-phosphate
30	Calcium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains calcium fluoride
31	Sodium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium fluoride
32	Potassium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium fluoride
33	Ammonium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains ammonium fluoride
34	Aluminium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains aluminium fluoride
35	Stannous fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains stannous fluoride
36	Hexadecyl ammonium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains hexadecyl ammonium fluoride

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
37	3-(N-Hexadecyl-N-2-hydroxy-ethylammonio) propyl-bis (2-hydroxy-ethyl) ammonium difluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains 3-(N-Hexa-decyl-N-2-hydroxyethy-lammonio) propylbis (2-hydroxy-ethyl) ammo-nium difluo-ride
38	NN'N'-Tris(polyox-yethylene)-N-hexa-decylpropyl enediamine dihydrofluo-ride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains NN'N'-Tris-(polyoxyethyl ene)-N-hexa-decylpropyle nediamine dihydrofluo-ride
39	Octadecen-ylammo-nium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains octadecyl-ammonium fluoride
40	Sodium flu-orosilicate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium fluorosilicate
41	Potassium fluorosili-cate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium fluorosilicate
42	Ammonium fluorosili-cate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains ammonium fluorosilicate
43	Magnesium fluorosili-cate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains magnesium fluorosilicate

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
44	1, 3-Bis(hydroxymethyl) imidazolidine-2-thione	(a) Hair care preparations (b) Nail care preparations	(a) Up to 2% (b) Up to 2%	(a) Prohibited in aerosols dispensers (sprays) (b) The pH of the product as applied must be less than 4	- Contains 1, 3-bis (hydroxymethyl) imidazolidine -2-thione
45	Benzyl alcohol	Solvents, perfumes and flavouring			
46	6-Methyl-coumarin	Oral hygiene products	0.003%		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%	**Thailand only** 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%	- Contains nicomethanol hydrofluoride
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		- Contains silver nitrate - Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Anti-dandruff shampoo	1%		- Contains selenium disulphide

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
					- Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	■ 20% as anhydrous aluminium zirconium chloride hydroxide ■ 5.4% as zirconium	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1 3. Prohibited in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis (8-hydroxy-quinolinium) sulphate	■ Stabilizer for hydrogen peroxide in rinse-off hair care preparations ■ Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations	■ 0.3% calculated as base ■ 0.03% calculated as base		

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as a % of ethanol and isopropyl alcohol		
53	Etidronic acid and its salts (1-hydroxy-ethylidene-diphosp-honic acid and its salts)	(a) Hair-care (b) Soap	(a) 1.5% expressed as etidro-nic acid (b) 0.2% expressed as etidro-nic acid		
54	1-Phenoxy-propan-2-ol	- Rinse-off products only - Prohibited in oral hygiene products	2%	As a preserva-tive, see Part IV, N° 43	-
55	Entry deleted				
56	Magnesium fluoride	Dental hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentra-tion must not exceed 0.15%	**Thailand only** 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%	- Contains magnesium fluoride
57	Strontium chloride hexahydrate	(a) Tooth-paste	(a) 3.5% calculated as strontium.	-	- Contains strontium chloride

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
		(b) Shampoo and face care products	When mixed with other permitted strontium products the total strontium content must not exceed 3.5% (b) 2.1% calculated as strontium. When mixed with other permitted strontium com-pounds, the total strontium content must not exceed 2.1%		- Frequent use by children is not advisable
58	Strontium acetate hemi-hydrate	Toothpaste	3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.5%		- Contains strontium acetate - Frequent use by children is not advisable

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
59	Talc: Hydrated magnesium silicate	(a) Powdery products intended to be used by children (b) Other products			(a) - Keep powder away from children's nose and mouth
60	Fatty acid diakyla-mides and dialkano-lamides		Maximum secondary amine content: 0.5%	- Do not use with nitrosating systems - Maximum secondary amine content: 5% (applies to raw materials) - Maximum nitrosamine content 50 µg/kg - Keep in nitrite-free containers	
61	Monoal-kylamines, monoalka-nolamines and their salts		Maximum secondary amine content: 0.5%	- Do not use with nitrosating systems - Minimum purity: 99% - Maximum secondary amine content: 0.5% (concerns raw materials) - Maximum nitrosamine content: 50 µg/kg	

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
				- Keep in nitrite-free containers	
62	Trialkylamines trialkanolamines and their salts	(a) non-rinse-off products (b) other products	(a) 2.5%	(a) (b): - Do not use with nitrosating systems - Minimum purity : 99% - Maximum secondary amine content: 0.5% (concerns raw materials) - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite free containers	
63	Strontium hydroxide	pH-regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		- Keep out of reach of children - Avoid contact with the eyes
64	Strontium hydroxide	Rinse-off hair care preparations professional use	4.5% calculated as strontium in the ready-for use preparation	All products must meet the hydrogen peroxide release requirements	- Avoid contact with eyes - Rinse eyes immediately if product comes into contact with them

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
					- For professional use only - Wear suitable gloves
65	Benzalkonium chloride, bromide and saccharinate	(a) Rinse-off hair (head) care products (b) Other products	(a) 3% (as benzalkonium chloride) (b) 0.1% (as benzalkonium chloride)	(a) In the final products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C_{14}, or less must not exceed 0.1% (as benzalkonium chloride)	(a) Avoid contact with the eyes (b) Avoid contact with the eyes
66	Polyacrylamides	(a) Body-care leave-on products (b) Other cosmetic products		(a) Maximum residual acrylamide content: 0.1 mg/kg (b) Maximum residual acrylamide content: 0.5 mg/kg	
				-	
				-	
93	2, 4-Diamino-pyrimidine-3-oxide	Hair care formulations	1.5%		
94	Benzoyl-peroxide	Artificial nail systems	0.7% (After mixing for use)	Professional use only	- For professional use only - Avoid skin contact

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
					- Read directions for use carefully
95	Hydro-quinone methylether	Artificial nail systems	0.02% (After mixing for use)	Professional use only	- For profes-sional use only - Contains hydroqui-none, do not use on children under the age of 12 years - Avoid skin contact - Read directions for use carefully
96	Musk xylene	All cosmetic products, with the exception of oral care products	(a) 1.0% in fine fragrance (b) 0.4% in eau de toilette (c) 0.03% in other products		
97	Musk ketone	All cosmetic products, with the exception of oral care products	(a) 1.4% in fine fragrance (b) 0.56% in eau de toilette (c) 0.042% in other products		

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
98	Salicylic acid ([7])	(a) Rinse-off hair products (b) Other products	(a) 3.0% (b) 2.0%	Not to be used in preparations for children under 3 years of age, except for shampoo For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	Not to be used for children under 3 years of age[8]
99	Inorganic sulphites and bisulphites ([9])	(a) Oxidative hair dye products (b) Hair straightening products (c) Self tanning products for the face (d) Other self tanning products	(a) 0.67% expressed as free SO_2 (b) 6.7% expressed as free SO_2 (c) 0.45% expressed as free SO_2 (d) 0.40% expressed as free SO_2	For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	
100	Triclocarban([10])	Rinse-off products	1.5%	Purity criteria: 3, 3', 4, 4'-Tetrachloroazobenzene $\leq$1 ppm 3, 3', 4, 4'-Tetrachloroazoxybenzene $\leq$ 1 ppm	

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
				For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	
101	Zinc pyri-thione[11]	Leave-on hair products	0.1%	For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	
A1	Camphor	Body powder		Not for use in products for children under the age of 3 years	Contains camphor - Not for use in products for children under the age of 3 years
A2	Menthol	Leave on products		Not for use in leave-on products for children under the age of 3 years	Contains menthol - Not for use in products for children under the age of 3 years
A3	Deleted				
A4	Persulp-hates of ammonium, potassium or sodium	Hair bleaching products	45% Persulphate before mixing with hydrogen		Avoid contact with eyes. Test for allergic reaction before use. Stop using

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
			peroxide. Not to exceed 20% after mixing		and rinse with water if irritation, burning or rash occurs at contact area. Do not use if there is scratch on scalp or dermatitis. Do not scratch heavily during hair wash. Keep out of reach of children and in a cool place.

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

(2) Only if the concentration exceeds 0.05 %.

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

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

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

(6) The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column d.

(7) As a preservative, see Part IV, No. 3.

(8) Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

(9) As a preservative, see Part IV, No. 9.

(10) As a preservative, see Part IV, No. 23.

(11) As a preservative, see Part IV, No. 8.

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
1	Basic blue 7	Non-oxidising colouring agents for hair dyeing	0.2 %		Can cause allergic reaction	30/06/2008
2	2-Amino-3-nitrophenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
3	4-Amino-3-nitrophenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
4	2, 7-Naphthalenediol and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
5	m-Amino-phenol and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
6	2, 6-Dihydroxy-3, 4-dimethyl-pyridine and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
7	4-Hydroxy-propylamino-3-nitrophenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 5.2 % (b) 2.6 %	In combination with hydrogen peroxide the maximum concentration upon application is 2.6 %	(a) (b) Can cause allergic reaction	30/06/2008
8	6-Nitro-2, 5-pyridine-diamine (CAS No. 69825-83-8) and its salts	Non-oxidising colouring agents for hair dyeing	3.0 %		Can cause allergic reaction	30/06/2008
9	HC Blue No. 11 and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
		(b) Non-oxidising colouring agents for hair dyeing				
10	Hydroxy-ethyl-2-nitro-p-toluidine and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	(a) (b) Can cause allergic reaction	30/06/2008
11	2-Hydroxy-ethylpicramic acid and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
12	p-Methyl-amino-phenol and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	Can cause allergic reaction	30/06/2008
13	2, 4-Diamino-5-methylphenoxyethanol and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum	Can cause allergic reaction	30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
				concentration upon application is 1.5 %		
14	HC Violet No. 2 and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
15	Hydroxy-ethyl-2, 6-dinitro-p-anisidine and its salts	Non-oxidising colouring agents for hair dyeing	3.0 %		Can cause allergic reaction	30/06/2008
16	HC Blue No. 12 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1.5 % (b) 1.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.75 %	(a) (b) Can cause allergic reaction	30/06/2008
-						
18	1, 3-Bis-(2,4-diaminophenoxy) propane and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
19	3-Amino-2, 4-dichloro-phenol and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
20	Phenyl-methylpy-razolone and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %	Can cause allergic reaction	30/06/2008
21	2-Methyl-5-hydroxy-ethylamino-phenol and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
22	Hydroxy-benzomor-phaline and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
-						

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
24	HC Yellow No. 10 and its salts	Non-oxidising colouring agents for hair dyeing	0.2 %			30/06/2008
25	2,6-Dimethoxy -3,5-pyridine-diamine and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %	Can cause allergic reaction	30/06/2008
26	HC Orange No. 2 and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			30/06/2008
27	HC Violet No. 1 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %		30/06/2008
28	3-Methyl-amino-4-nitro-phenoxy-ethanol and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			30/06/2008
29	2-Hydroxy-ethylamino -5-nitro-anisole and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
30	2-Chloro-5-nitro-N-hydroxy-ethyl-p-phenylene-diamine and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
31	HC Red No. 13 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.5 % (b) 2.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.25 %		30/06/2008
32	1, 5-Naphthalenediol and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008
33	Hydroxypropyl bis (N-hydroxyethyl-p-phenylene-diamine) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	Can cause allergic reaction	30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
34	o-Amino-phenol and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
35	4-Amino-2-hydroxyto-luene and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
36	2, 4-Diamino-phenoxy-ethanol and its salts	Oxidising colouring agents for hair dyeing	4.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 2.0 %		30/06/2008
37	2-Methyl-resorcinol and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
38	4-Amino-m-cresol and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
				concentration upon application is 1.5 %		
39	2-Amino-4-hydroxyethylaminoanisole and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
-						
41	6-Amino-o-cresol and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
43	Hydroxyethylaminomethyl-p-aminophenol and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
44	Hydroxyethyl-3, 4-methylenedioxyaniline and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
45	Acid Black 52 and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
46	2-Nitro-p-phenylenediamine and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.15 %		30/06/2008
47	HC Blue No. 2 and its salts	Non-oxidising colouring agents for hair dyeing	2.8 %			30/06/2008
48	3-Nitro-p-hydroxyethylaminophenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 6.0 % (b) 6.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 3.0 %		30/06/2008
49	4-Nitrophenyl aminoethylurea and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the maximum		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
		(b) Non-oxidising colouring agents for hair dyeing		concentration upon application is 0.25 %		
50	HC Red No. 10 + HC Red No. 11 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
51	Yellow No. 6 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
52	HC Yellow No. 12 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1.0 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008
53	HC Blue No. 10 and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
				maximum concentration upon application is 1.0 %		
54	HC Blue No. 9 and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
55	2-Chloro-6-ethylamino-4-nitro phenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
56	2-Amino-6-chloro-4-nitrophenol and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
57	Basic Blue 26 (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the		30/06/2008

Ref. #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
		(b) Non-oxidising colouring agents for hair dyeing		maximum concentration upon application is 0.25 %		
58	Acid Red 33 (CI 17200) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
59	Ponceau SX (CI 14700) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
60	Basic Violet 14 (CI 42510) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.15 %		30/06/2008

Part III (regulation 7(3)(a))

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS[1]

Field of application

Column 1 : Colouring agents allowed in all cosmetic products.

Column 2 : Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and eye make-up remover.

Column 3 : Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes.

Column 4 : Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
10006	Green				X	
10020	Green			X		
10316 ([2])	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
12085 ([2])	Red	X				3 % max. concentration in the finished products
12120	Red				X	
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				
14720	Red	X				
14815	Red	X				

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
15510 (2)	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 (2)	Red	X				3 % max. concentration in the finished products
15800	Red			X		
15850 (2)	Red	X				
15865 (2)	Red	X				
15880	Red	X				
15980	Orange	X				
15985 (2)	Yellow	X				
16035	Red	X				
16185	Red	X				
16230	Orange			X		
16255 (2)	Red	X				
16290	Red	X				
17200 (2)	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 (2)	Yellow	X				
20040	Yellow				X	Maximum 3, 3'- dimethyl-benzidine concentration in the colouring agent: 5 ppm
20470	Black				X	
21100	Yellow				X	Maximum 3, 3'-dimethyl-benzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	Ditto
21230	Yellow			X		

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
24790	Red				X	
26100	Red			X		Purity criteria: aniline ≤ 0.2 % 2-naphtol ≤ 0.2 % 4-aminoazobenzene ≤ 0.1 % 1-(phenylazo)-2-naphtol ≤ 3 % 1-[2-(phenylazo)phenylazo]-2-naphtalenol ≤ 2 %
27755	Black	X				
28440	Black	X				
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				
40825	Orange	X				
40850	Orange	X				
42045	Blue			X		
42051 (2)	Blue	X				
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	5 ppm max. concentration in the finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				
45100	Red				X	
45190	Violet				X	
45220	Red				X	
45350	Yellow	X				6 % max. concentration in the finished product
45370 (2)	Orange	X				Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
45380 (2)	Red	X				Ditto
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 %
45405	Red		X			Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)-benzoic acid
45410 (2)	Red	X				Ditto
45430 (2)	Red	X				Ditto
47000	Yellow			X		
47005	Yellow	X				
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				
73360	Red	X				
73385	Violet	X				
73900	Violet				X	
73915	Red				X	

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				
75125	Yellow	X				
75130	Orange	X				
75135	Yellow	X				
75170	White	X				
75300	Yellow	X				
75470	Red	X				
75810	Green	X				
77000	White	X				
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				
77288	Green	X				Free from chromate ion
77289	Green	X				Free from chromate ion
77346	Green	X				
77400	Brown	X				
77480	Brown	X				
77489	Orange	X				
77491	Red	X				
77492	Yellow	X				
77499	Black	X				

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
77510	Blue	X				Free from cyanide ion
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				
77891	White	X				
77947	White	X				
Acid Red 195	Red			X		
Aluminium, zinc, magnesium and calcium stearates	White	X				
Anthocyanins	Red	X				
Beetroot red	Red	X				
Bromocresol green	Green				X	
Bromothymol blue	Blue				X	
Capsanthin, Capsorubin	Orange	X				
Caramel	Brown	X				
Guiazulene[3]	Blue		X			
Lactoflavin	Yellow	X				

(1) Lakes or salts of these colouring agents using substances not prohibited under Part I.

(2) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in regulation 10.

(3) Adopted during the Fifth ASEAN Cosmetic Committee Meeting.

Part IV (regulation 7(4)(a))

LIST OF PRESERVATIVES ALLOWED

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid, and its sodium salt	Rinse off products, except oral care products; 2.5 % (acid) Oral care products; 1.7 % (acid) Leave on products; 0.5 % (acid)		
1a	Salts of benzoic acid other than those listed under reference number 1 and esters of benzoic acid	0.5 % (acid)		
2	Propionic acid and its salts	2 % (acid)		
3	Salicylic acid and its salts (+)[1]	0.5 % (acid)	Not to be used in preparations for children under 3 years of age, except for shampoos	Not to be used for children under 3 years of age [2]
4	Sorbic acid (hexa-2, 4-dienoic acid) and its salts	0.6% (acid)		
5	Formaldehyde and paraformaldehyde (+)	0.2 % (except for products for oral hygiene) 0.1 % (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
7	Biphenyl-2-ol (o-phenylphenol) and its salts	0.2 % expressed as phenol		
8	Zinc pyrithione (+)[3]	Hair products; 1.0 % Other products; 0.5 %	Rinse off products only. Not for use in products for oral care	
9	Inorganic sulphites and hydrogensulphites (+)[4]	0.2 % expressed as free SO_2		
10	Entry deleted			
11	Chlorobutanol (INN)	0.5 %	Prohibited in aerosol dispensers (sprays)	- Contains chlorobutanol
12	4-Hydroxybenzoic acid its salts and esters	0.4 % (acid) for 1 ester; 0.8 % (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts	0.6 % (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt	0.5 % (expressed as acid)		
15	3, 3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
16	Thiomersal (INN)	0.007 % (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007 %	For eye make-up and eye make-up remover only	- Contains thiomersal
17	Phenylmercuric salts (including borate)	Ditto	Ditto	- Contains phenyl-mercuric compounds
18	Undec-10-enoic acid and salts (+)	0.2 % (acid)		
19	Hexetidine (INN)	0.1 %		
20	5-Bromo-5-nitro-1,3 dioxane	0.1 %	Rinse off products only. Avoid formation of nitrosamines	
21	Bronopol (INN)	0.1 %	Avoid formation of nitrosamines	
22	2, 4-Dichlorobenzyl alcohol	0.15 %		
23	Triclocarban (INN) (+)[5]	0.2 %	Purity criteria: 3, 3', 4, 4'-Tetrachloroazo-benzene less than 1 ppm; 3, 3',4, 4'-Tetrachloro-azoxybenzene less than 1 ppm	

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
24	4-Chloro-m-cresol	0.2 %	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan (INN) (+)	0.3 %		
26	4-Chloro-3, 5-xylenol	0.5 %		
27	3, 3'-Bis(1-hydroxy-methyl-2, 5-dioxoi-midazolidin-4-yl)-1, 1'- methylenediurea ("Imidazolidinyl urea")	0.6 %		
28	Poly(1-hexamethylenebiguanide hydrochloride)	0.3 %		
29	2-Phenoxyethanol	1.0 %		
30	Hexamethylenetetramine (methenamine) (INN)	0.15%		
31	Methenamine 3-chloroallylochloride (INNM)	0.2%		
32	1-(4-Chloro-phenoxy)-1-(imidazol-1-yl) 3, 3-dimethylbutan-2-one (+)	0.5%		
33	1, 3-Bis-(hydroxymethyl) 5, 5-dimethylimi-dazolidine-2, 4-dione	0.6%		

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
34	Benzyl alcohol (+)	1 %		
35	1-Hydroxy-4-methyl-6(2, 4, 4-trimethylpentyl)-2-pyridon and its monoethanolamine salt (+)	1 % 0. 5%	Products rinsed off. For other products	
36	Entry deleted			
37	6, 6-Dibromo-4, 4-dichloro-2, 2'-methylenediphenol: Bromochlorophen	0.1 %		
38	4-Isopropyl-m-cresol	0.1 %		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methy-lisothiazol-3(2H)-one with magne-sium chloride and magnesium nitrate	0.0015 % (of a mixture in the ratio 3:1 of 5-Chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one)		
40	2-Benzyl-4-chlo-rophenol (Chlorophene)	0.2 %		
41	2-Chloroacetamide	0.3 %		- Contains chloroace-tamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3 % expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol (+)	1.0 %	Only for rinse off products	

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (+)	0.1 %		
45	4, 4-Dimethyl-1, 3-oxazolidine	0.1 %	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxy-methyl-1, 3-dioxo-2, 5-imidazolinidyl-4)-N'-(hydroxymethyl) urea	0.5 %		
47	1, 6-Di(4-amidino-phenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy- benzoate (+)	0.1 %		
48	Glutaraldehyde (Pentane-1, 5-dial)	0.1 %	Prohibited in aerosols (sprays)	- Contains glutaralde-hyde (where glutaralde-hyde con-centration in the finished product exceeds 0.05%)
49	5-Ethyl-3, 7-dioxa-1-azabicyclo [3.3.0] octane	0.3 %	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
50	3-(p-Chlorophe-noxy)-propane-1, 2-diol (chlorphenesin)	0.3 %		
51	Sodium hydroxy-methylamino acetate (Sodium hydroxymethylgly-cinate)	0.5 %		
52	Silver chloride deposited on Titanium dioxide	0.004 % calculated as AgCl	20% AgCl (w/w) on TiO_2 Prohibited in products for children under 3 years of age, in oral hygiene products and in products intended for application around the eyes and on the lips	
53	Benzethonium chloride (INCI)	0.1 %	(a) Rinse-off products only (b) Leave on products other than for oral care use	
54	Benzalkonium chloride, bromide and saccharinate*	0.1 % calculated as Benzalkonium chloride		Avoid contact with the eyes
55	Benzylhemiformal	0.15 %	Only for products to be removed by rinsing	
56	iodopropynyl butyl-carbamate (IPBC) 3-iodo-2-propynyl-butylcarbamate	(a) rinseoff products: 0.02 %	Not to be used in oral hygiene and lip care products	(a) Not to be used for children under 3 years of age (**)

Ref. Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
		(b) leave on products: 0.01 % except in deodorants & antiperspirants: 0.0075 %	(a) Not to be used in preparations for children under 3 years of age, except in bath products/ shower gels and shampoo (b) Not to be used in body lotion and body cream (*) Not to be used in preparations for children under 3 years of age.	(b) Not to be used for children under 3 years of age (***)
57	Methylisothiazo-linone (INCI)	0.01%		

1. For non-preservative usage see Part II, No. 98.

2. Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

3. For non-preservative usage see Part II, No. 101.

4. For non-preservative usage see Part II, No. 99.

5. For non-preservative usage see Part II, No. 100.

(*) Concerns any products aimed to be applied on a large part of the body.

(**) Solely for products, other than bath products/shower gels and shampoo, which might be used for children under 3 years of age.

(***) Solely for products which might be used for children under 3 years of age.

Part V (regulation 7(5)(a))

LIST OF PERMITTED FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

Ref. Number	Substance	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	4-Aminobenzoic acid	5 %		
2	N, N, N-Trimethyl-4-(2-oxoborn-3-ylidene methyl) anilinium methyl sulphate	6 %		
3	Homosalate (INN)	10 %		
4	Oxybenzone (INN)	10 %		Contains oxybenzone[1]
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (expressed as acid)		
7	3, 3'-(1, 4-Phenylene-dimethylene)bis(7, 7-dimethyl-2-oxo-bicyclo-[2, 2,1]hept-1-yl methanesulphonic acid) and its salts	10 % (expressed as acid)		
8	1-(4-Tert-butylphenyl)-3-(4-methoxyphenyl)-propane-1, 3-dione	5 %		
9	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6 % (expressed as acid)		
10	2-Cyano-3, 3-diphenylacrylic acid, 2-ethylhexyl ester (Octocrylene)	10 % (expressed as acid)		
11	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene) methyl] benzyl} acrylamide	6 %		

Ref. Number	Substance	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
12	Octyl methoxycinnamate	10 %		
13	Ethoxylated-ethyl-4-aminobenzoate (PEG-25 PABA)	10 %		
14	Isopentyl-4-methoxy-cinnamate (Isoamyl p-methoxycinnamate)	10 %		
15	2, 4, 6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1, 3, 5-triazine (Octyl triazone)	5 %		
16	Phenol, 2-(2H-benzo-triazol-2-yl)-4-methyl-6-(2-methyl-3-(1, 3, 3, 3-tetramethyl-1-(trimethy-lsilyl)oxy)-disiloxanyl)-propyl (Drometrizole Trisiloxane)	15 %		
17	Benzoic acid, 4, 4-((6-(((1, 1-dimethylethyl)-amino)-carbonyl)phenyl) amino)-1, 3, 5-triazine-2, 4-diyl)-diimino)bis-, bis-(2-ethylhexyl)ester)	10 %		
18	3-(4'-Methylbenzy-lidene)-d-1 camphor (4-Methylbenzylidene Camphor)	4 %		
19	3-Benzylidene camphor (3-Benzylidene camphor)	2 %		
20	2-Ethylhexyl salicylate (Octyl Salicylate)	5 %		
21	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8 %		

Ref. Number	Substance	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
22	2-Hydroxy-4-methoxy-benzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt	5 % (of acid)		
23	2, 2'-Methylene-bis-6-(2H-benzotriazol-2yl)-4-(tetramethyl-butyl)-1, 1, 3, 3-phenol	10 %		
24	Monosodium salt of 2-2'-bis-(1, 4-phenylene)1H-benzimidazole-4, 6-disulphonic acid	10 % (of acid)		
25	(1, 3, 5)-Triazine-2, 4-bis{(4-(2-ethyl-hexyloxy)-2-hydroxy)-phenyl}-6-(4-methoxyphenyl)	10 %		
26	Dimethicodiethytlbenzal-malonate (CAS No. 207574-74-1) INCI Polysilicone - 15	10 %		
27	Titanium dioxide	25 %		
28	Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl]-, hexylester (INCI Name; Diethylamino Hydroxybenzoyl Hexyl Benzoate;	10 % in sunscreen products		
A28	Methyl anthranilate	5 %		
A29	Zinc oxide	25 % in sunscreen products		

1. Not required if concentration is 0.5 % or less and when it is used only for product protection purposes.

SECOND SCHEDULE (regulation 8(1))

ASEAN COSMETIC LABELLING REQUIREMENTS

A. OBJECTIVE

This document provides guidance for the labelling requirements of cosmetic products to which Regulation 8(1) apply.

B. SCOPE AND DEFINITIONS

1. For the purpose of this document:

Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trade mark or the name of the manufacturer;

Immediate packaging means the container or other form of packaging immediately in contact with the cosmetic product;

Outer packaging means the packaging into which is placed the immediate packaging;

Labelling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.

C. LABELLING OF COSMETIC PRODUCTS

1. The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:

(a) The name of the cosmetic product and its function, unless it is clear from the presentation of the product;

(b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation;

(c) Full ingredient listing. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavour". Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Part III.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms "may contain" or "+/-" be added.

The ingredients shall be specified using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated.

The following shall not, however, be regarded as ingredients:

- Impurities in the raw materials used;
- Subsidiary technical materials used in the preparation but not present in the final products;
- Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions.

(d) Country of manufacture;

(e) The name and address of the company or person responsible for placing the product on the local market;

(f) The contents given by weight or volume, in either metric or both metric and imperial system;

(g) The manufacturer's batch number;

(h) The manufacturing or the expiry date of the product in clear terms (e.g. month/year). The date shall be clearly expressed and shall consist either of the month and year or the day, month and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with article 3. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the expiry date shall be mandatory for cosmetic products the minimum durability of which is less than 30 months.

(i) Special precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label in First Schedule __", which must appear on the label as well as any special precautionary information on the cosmetic products.

Member countries may require specific warnings based on local needs for declaration of ingredients from animal origin. In this case:

(i) There must be a statement (of any format) on the product label signalling the presence of ingredients of animal origin;

(ii) For ingredients of bovine or porcine origin, the exact animal must be declared.

2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in paragraphs 1 (a) - (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However the following particulars at least shall appear on small immediate packaging:

(a) The name of the cosmetic product;

(b) The manufacturer's batch number;

3. The particulars referred to in paragraphs 1 and 2 shall be easily legible, clearly comprehensible and indelible;

4. The particulars listed in paragraph 1 shall appear in English and/or national language and/or a language understood by the consumer where the product is marketed. Member countries may require that the information in paragraphs a), b), e), f) and i) be in the national language or a language easily understood by the consumer.

APPENDIX A

List of Standard References to be used for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary;
2. British Pharmacopeia;
3. United States Pharmacopeia;
4. Chemical Abstract Services.

THIRD SCHEDULE (regulation 8(1))

ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE

PREAMBLE

The GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive. As this document is particularly intended for cosmetic products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

The Good Manufacturing Practices presented here is only a general guideline for the manufacturers to develop its own internal quality management system and procedures. The important objective must be met in any case, i.e. the final products must meet the quality standards appropriate to their intended use to assure consumer's health and benefit.

1. INTRODUCTION

The objective of the Cosmetic Good Manufacturing Practice (GMP) guidelines is to ensure that products are consistently manufactured and controlled to the specified quality. It is concerned with all aspects of production and quality control.

1.1 General Consideration

1.1.1 In the manufacture of cosmetic products, overall control and monitoring is essential to ensure that the consumer receives products of specified quality.

1.1.2 The quality of a product depends on the starting materials, production and quality control processes, building, equipment and personnel involved.

1.2 Quality Management System

1.2.1 A quality system should be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organisational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.

1.2.2 The quality system should be structured and adapted to the company's activities and to the nature of its products and should take into consideration appropriate elements stated in this Guidelines.

1.2.3 The quality system operation should ensure that if necessary, samples of starting materials, intermediate, and finished products are taken, tested to determine their release or rejection on the basis of test results and other available evidence related to quality.

2. PERSONNEL

There should be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

2.1 Organisation, Qualification and Responsibilities

2.1.1 The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.

2.1.2 The head of production should be adequately trained and experienced in cosmetic manufacturing.

He should have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records.

2.1.3 The head of quality control should be adequately trained and experienced in the field of quality control. He should be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures. He should have the authority to designate/ assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions.

2.1.4 The responsibilities and authority of key personnel should be clearly defined.

2.1.5 An adequate number of trained personnel should be appointed to execute direct supervision in each section of the production and the quality control unit.

2.2 Training

2.2.1 All personnel directly involved in the manufacturing activities should be appropriately trained in manufacturing operations in accordance to GMP principles. Special attention should be given to training of personnel working with any hazardous materials.

2.2.2 Training in GMP should be conducted on a continuous basis.

2.2.3 Records of training should be maintained and its effectiveness assessed periodically.

3. PREMISES

The premises for manufacturing should be suitably located, designed, constructed and maintained.

3.1 Effective measures should be taken to avoid any contamination from the surrounding environment and from pests.

3.2 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises and equipment provided that due care should be exercised to prevent cross contamination and risk of mix-up.

3.3 Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.

3.4 Appropriate changing rooms and facilities should be provided. Toilets should be separated from the production areas to prevent product contamination/cross contamination.

3.5 Defined areas should be provided for, wherever possible and applicable:

3.5.1 Materials receiving.

3.5.2 Material sampling.

3.5.3 Incoming goods and quarantine.

3.5.4 Starting materials storage.

3.5.5 Weighing and dispensing.

3.5.6 Processing.

3.5.7 Storage of bulk products.

3.5.8 Packaging.

3.5.9 Quarantine storage before final release of products.

3.5.10 Storage of finished products.

3.5.11 Loading and unloading.

3.5.12 Laboratories.

3.5.13 Equipment washing.

3.6 Wall and ceiling, where applicable should be smooth and easy to maintain. The floor in processing areas should have a surface that is easy to clean and sanitise.

3.7 Drains should be of adequate size and should have trapped gullies and proper flow. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection.

3.8 Air intakes and exhausts and associated pipework and ducting, when applicable, should be installed in such a way as to avoid product contamination.

3.9 Buildings should be adequately lit and properly ventilated appropriate to the operations.

3.10 Pipework, light fittings, ventilation points and other services in manufacturing areas should preferably be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.

3.11 Laboratories should preferably be physically separated from the production areas.

3.12 Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.

3.12.1 Such areas should be suitable for effective separation of quarantined materials and products. Special and segregated areas should be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.

3.12.2 Where special storage conditions e.g. temperature, humidity and security are required, these should be provided.

3.12.3 Storage arrangements should permit separation of different labels and other printed materials to avoid mix-up.

4. EQUIPMENT

Equipment should be designed and located to suit the production of the product.

4.1 Design and Construction

4.1.1 The equipment surfaces coming into contact with any in-process material should not react with or absorb the materials being processed.

4.1.2 Equipment should not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.

4.1.3 Equipment should be easily cleaned.

4.1.4 Equipment used for flammable substances should be explosion proof.

4.2 Installation and Location

4.2.1 Equipment should be located to avoid congestion and should be properly identified to assure that products do not become admixed or confused with one another.

4.2.2 Water, steam and pressure or vacuum lines, where applicable, should be installed so as to be easily accessible during all phases of operation. They should be clearly identified.

4.2.3 Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled), steam, compressed air and gases (example nitrogen) should function as designed and identifiable.

4.3 Maintenance

Weighing, measuring, testing and recording equipment should be serviced and calibrated regularly. All records should be maintained.

5. SANITATION AND HYGIENE

Sanitation and hygiene should be practised to avoid contamination of the manufacturing of products. It should cover personnel, premises, equipment/ apparatus and production materials and containers.

5.1 Personnel

5.1.1 Personnel should be healthy to perform their assigned duties. Regular medical examination must be conducted for all production personnel involved with manufacturing processes.

5.1.2 Personnel must practise good personal hygiene.

5.1.3 Any personnel shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle raw materials, packaging materials, in-process materials, and finished products.

5.1.4 Personnel should be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the products.

5.1.5 Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire appropriate to the duties they perform.

5.1.6 Smoking, eating, drinking and chewing, food, drinks and smoking materials and other materials that might contaminate are not permitted in production, laboratory, storage or other areas where they might adversely affect product quality.

5.1.7 All authorised personnel entering the production areas should practice personal hygiene including proper attire.

5.2 Premises

5.2.1 Adequate employee's washing and well ventilated toilet facilities should be provided and separated from the production area.

5.2.2 Suitable locker facilities should be provided at appropriate location for the storage of employees' clothing and personal belongings.

5.2.3 Waste material should be regularly collected in suitable receptacles for removal to collection points outside the production area.

5.2.4 Rodenticides, insecticides, fumigating agents and sanitising materials must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products.

5.3 Equipment and Apparatus

5.3.1 Equipment and utensils should be kept clean.

5.3.2 Vacuum or wet cleaning methods are preferred. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.

5.3.3 Standard operating procedures must be followed for cleaning and sanitising of major machines.

6. PRODUCTION

6.1 Starting Materials

6.1.1 Water

Special attention should be paid to water, since it is an important raw material. Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

6.1.2 Verification of materials

All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labelled. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

6.1.3 **Rejected materials**

Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

6.2 Batch Numbering System

6.2.1 Every finished product should bear a production identification number which enables the history of the product to be traced.

6.2.2 A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion.

6.2.3 Whenever possible, the batch number should be printed on the immediate and outer container of the product.

6.2.4 Records of batch number should be maintained.

6.3 Weighing and Measurement

6.3.1 Weighing should be carried out in the defined areas using calibrated equipment.

6.3.2 All weighing and measurement carried out should be recorded and, where applicable, counterchecked.

6.4 Procedure and Processing

6.4.1 All starting materials used should be approved according to specifications.

6.4.2 All manufacturing procedures should be carried out according to written procedures.

6.4.3. All required in-process controls should be carried out and recorded.

6.4.4 Bulk products should be properly labelled until approved by Quality Control, where applicable.

6.4.5 Particular attention should be paid to problem of cross contamination in all stages of processing.

6.5 Dry Products

Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

6.6 Wet Products

6.6.1 Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.

6.6.2 The use of closed systems of production and transfer is recommended.

6.6.3 Where pipe-lines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

6.7 Labelling and Packaging

6.7.1 Packaging line should be inspected for clearance prior to operation. Equipment should be clean and functional. All materials and products from previous packaging operation should have been removed.

6.7.2 Samples should be taken and checked at random during labelling and packaging operations.

6.7.3 Each labelling and packaging line should be clearly identified to avoid mix-up.

6.7.4 Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly.

6.8 Finished Product: Quarantine and Delivery to Finished Stock

6.8.1 All finished products should be approved by Quality Control prior to release.

7. QUALITY CONTROL

7.1 Introduction

Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

7.1.1 A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

7.1.2 Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

7.2 Reprocessing

7.2.1 The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.

7.2.2 Additional testing of any finished product which has been reprocessed should be performed.

7.3 Returned Products

7.3.1 Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.

7.3.2 All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.

7.3.3 Returned products which do not comply with the original specification should be rejected.

7.3.4 Rejected products should be disposed according to appropriate procedures.

7.3.5 Records of returned products must be maintained.

8. DOCUMENTATION

8.1 Introduction

The documentation system should include the complete history of each batch, from starting materials to finished products. The system should record executed activities for maintenance, storage, quality control, primary distribution and other specific matters related to GMP.

8.1.1 There should be a system for preventing the use of any superseded document.

8.1.2 If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and correction is made close to the original entry, initialled and dated.

8.1.3 Where documents bear instructions they should be clearly written step by step.

8.1.4 Documents should be dated and authorised.

8.1.5 Documents should be readily available to relevant parties.

8.2 Specifications

All specifications should be approved by authorised personnel.

8.2.1 Raw and packaging material specifications should include:

(a) Name of material.

(b) Description of the material.

(c) Testing parameters and acceptance limits.

(d) Technical drawings, where applicable.

(e) Special precautions e.g. storage and safety conditions, if necessary.

8.2.2 Bulk and finished product specifications should include:

(a) Name of product.

(b) Description.

(c) Physical properties.

(d) Chemical assay and/or microbiological assays and their acceptance limits; if necessary.

(e) Storage conditions and safety precautions, if necessary.

8.3 Documents for Production

8.3.1 **Master Formula**

The Master formula should be available upon request. This document should contain the following information:

(a) Product name and product code/number.

(b) Intended packaging materials, and storage conditions.

(c) List of raw materials used.

(d) List of equipment used.

(e) In-process controls with their limits in processing and packaging, where applicable.

8.3.2 **Batch Manufacturing Record (BMR)**

(a) Batch Manufacturing Records should be prepared for each batch of product.

(b) Each BMR should include the following:

(i) Name of product.
(ii) Batch formula.
(iii) Brief manufacturing process.
(iv) Batch or code number.
(v) Date of the start and finish of processing and packaging.
(vi) Identity of individual major equipment and lines or location used.
(vii) Records of cleaning of equipment used for processing as appropriate.
(viii) In-process control and laboratory results, such as pH and temperature test records.
(ix) Packaging line clearance inspection records.

(x) Any sampling performed during various steps of processing.
(xi) Any investigation of specific failure or discrepancies.
(xii) Results of examinations on packed and labelled products.

8.3.3 **Records for Quality Control**

(a) Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained.

(b) These records may include:

(i) Date of test.
(ii) Identification of the material.
(iii) Supplier name.
(iv) Date of receipt.
(v) Original batch number if any.
(vi) Batch number.
(vii) Quality control number.
(viii) Quantity received.
(ix) Date of sampling.
(x) Quality control results.

9. INTERNAL AUDITS

An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purpose. Such internal audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each internal audit.

10. STORAGE

10.1 Storage Areas

10.1.1 Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.

10.1.2 Storage areas should be designed or adapted to ensure good storage conditions. They should be clean, dry and well-maintained. Where special storage conditions are required

(temperature and humidity) these should be provided, checked and monitored.

10.1.3 Receiving and dispatch bays should protect materials and products from weather. Reception areas should be designed and equipped to allow incoming materials to be cleaned if necessary before storage.

10.1.4 Storage areas for quarantine products should be clearly demarcated.

10.1.5 Wherever possible sampling area for starting materials should be provided to prevent contamination.

10.1.6 Hazardous materials should be safely and securely stored.

10.2 Stock Handling and Control

10.2.1 **Receiving Products**

10.2.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity.

10.2.1.2 The consignment should be carefully inspected for defects and damage. Records should be retained for each delivery.

10.2.2 **Control**

10.2.2.1 Records should be maintained showing all receipts and issues of products.

10.2.2.2 Issues should observe the principle of stock rotation (first in - first out).

10.2.2.3 All labels and containers of products should not be altered, tampered or changed.

11. CONTRACT MANUFACTURING AND ANALYSIS

The conditions of contract manufacturing and analysis should be clearly defined, agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards.

There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

12. COMPLAINTS

12.1 A person responsible for handling complaints and deciding the measures to be taken should be designated. If this person is different from the authorised person, the latter should be made aware of any complaint, investigation or recall.

12.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

12.3 Complaints involving product defects should be recorded with all the original details and investigated.

12.4 If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.

12.5 Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.

12.6 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

12.7 Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.

12.8 The competent authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration which may lead to serious safety issues.

13. PRODUCT RECALLS

There should be a system of recall from the market of products known or suspected to be defective.

13.1 A person responsible for the execution and co-ordination of recalls should be designated, as well as sufficient personnel, to handle all aspects of recalls with the appropriate degree of urgency.

13.2 Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly.

13.3 The primary distribution records should be readily available to the person(s) responsible for recalls, and they should contain sufficient information of distributors.

13.4 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.

13.5 The effectiveness of the arrangements for recalls should be evaluated from time to time.

13.6 A written instruction should be established to ensure recalled products are stored securely in a segregated area while awaiting decision.

14. GLOSSARY

14.1 Batch

A quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality.

14.2 Batch Number

A designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution.

14.3 Bulk Product

Any processed product which will have to undergo the packaging operation in order to become a finished product.

14.4 Calibration

Combination of checking an instrument and adjusting it to bring it within its limits for accuracy according to recognized standards.

14.5 Date of Manufacture

Date of manufacturing of a batch of product.

14.6 Documentation

All written procedures, instructions and records involved in the manufacture and quality control of products.

14.7 Product

Any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, in or for cleansing, improving, altering or beautifying the complexion, skin, hair or teeth.

14.8 Finished Product

A product which has undergone all stages of manufacturing operations.

14.9 In-Process Control

Checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on environment and equipment in order to ensure that the end product will comply with its specification.

14.10 Intermediate Product

Any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product.

14.11 Manufacture or Manufacturing

The complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.

14.12 Packaging

The part of production cycle applied to a bulk product to obtain the finished product.

14.13 Packaging Material

Any material used in the packaging of a bulk product to obtain the finished product.

14.14 Processing

The part of production cycle starting from weighing of raw materials to obtaining a bulk product.

14.15 Production

All operations starting from processing to packaging to obtain a finished product.

14.16 Quality Control

All measures taken during manufacturing which are designed to ensure the uniform output of product that will conform to established specifications.

14.17 Quarantine

The status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution.

14.18 Raw Materials

Any ingredient to be used in the formulation of a cosmetic product.

14.19 Rejected

The status of materials or products which are not permitted to be used for processing, packaging or distribution.

14.20 Released

The status of materials or products which are allowed to be used for processing, packaging or distribution.

14.21 Returned Product

Finished products sent back to the manufacturer.

14.22 Sanitation

Hygienic control on manufacturing premises, personnel, equipment and material handling.

14.23 Specification of Materials

A description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations.

14.24 Starting Materials

Raw materials and packaging materials used in the production of products.

15. REFERENCES

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15.2 Good Storage Practice, 1st Edition, January, 1995, ISBN 983-9870-14-9, National Pharmaceutical Control Bureau, Malaysia.

15.3 Cosmetic Good Manufacturing Practices, COLIPA - The European Cosmetic Toiletry and Perfumery Association, July, 1994.

15.4 Australian Code of Good Manufacturing Practice for Therapeutic Goods - Sunscreen Products, Therapeutic Goods Administration (TGA), Australia, February, 1994.

15.5 Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines, National Pharmaceutical Control Bureau, Malaysia, 1st Edition, 1999.

Made this 21st. day of Zulhijjah, 1428 Hijriah corresponding to the 31st. day of December, 2007.

PEHIN ORANG KAYA INDERA PAHLAWAN DATO SERI SETIA
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