



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
D.O.H. Compound
Alabang, Muntinlupa Metro Manila

September 4, 1997

BUREAU CIRCULAR
No. 12 series 1997

TO : ALL COSMETIC MANUFACTURERS, TRADERS, IMPORTERS AND PARTIES CONCERNED

SUBJECT : 1997 UPDATED LISTING OF COSMETIC INGREDIENTS

The BFAD Management Committee, in its meeting on August 28, 1997 has adopted and approved the updated technical standards and requirements set for cosmetic ingredients as recommended by the Joint BFAD and Cosmetic Industry Study Group's Technical Committee. As such, the sections of Bureau Circular No. 19-A series of 1997 hereunder described are amended by the listings of cosmetic ingredients hereunto appended, to wit:

Section III - Restricted Ingredients For Use In Cosmetics

Table I : List Of Substances Which Cosmetics Products Must Not Contain Except Subject To The Restrictions And Conditions Specified

Table II : List Of Preservatives Which Cosmetic Products May Contain Subject To The Restrictions And Conditions Specified

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Additionally, BFAD has decided to extend the approval of products containing benzethonium chloride only up to December 31, 1997 in view of the ban of the said ingredient under the European Economic Community's (EEC) August 1996 Directive, unless additional safety data on the same are found before December 31, 1997.

As provided for in Section IX of Bureau-Memorandum Circular 19-A s 1992, "the validity period of substances or ingredients provisionally allowed will automatically be considered extended until the same is either delisted/deleted as having been considered by BFAD as permissible or restricted substances in cosmetics."

This is for the information and guidance of all the parties concerned.

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Director**

TABLE I
Section 5.0 RESTRICTED INGREDIENTS

LIST OF SUBSTANCES WHICH COSMETICS PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN BUREAU CIRCULAR No. 12 s. 1997

REF NO.	SUBSTANCE	Field of applications and/or use	Maximum allowable concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the label
1	Boric Acid/Sodium Borate (Borax)	a) Talcs/Facial Cleansers b) Products for oral hygiene c) Other products	a) 5% b) 0.5% c) 3%	a) Not to be used in products for children under three years of age	a) Not to be used for children under three years of age See section 1.4.G
2	Thioglycollic acid and its salts	a) Hair waving or straightening products: - general use - professional use b) Depilatories c) Other hair care products which are removed after application	-8% ready for use pH 7-9.5 -11% ready for use pH 7-9.5 pH 7-12.7 -2% ready for use pH 7-9.5 Percentages calculated as thioglycollic acid/		a) Contains thioglycolate. - Follow the instructions - Keep out of reach of children - Avoid contact with eyes, rinse immediately with plenty of water and consult a physician - For professional use only. - Wear suitable gloves. b) and c) c) - Contains thioglycolate. - Follow the instructions - Keep out of reach of children a) b) c) See 1.4.1.
3	Thioglycollic acid esters	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		- Contains thioglycolate. - Follow the instructions - Keep out of reach of children - Warning shall be the same as Thioglycollic acid and its salts - For professional use only - Wear suitable gloves See 1.4.1
4	a) Biosulfur fluid b) Sulfur	Liquid Shampoos	0.5-2.0% >2.0%		
5	Low molecular wt. Hydrocarbon i.e. - propane	Aerosol propellant for cosmetic appearing in the foam or paste	10%	Water content in the cosmetic is not less than 40% of the total mass & the propellant is not more than 10% of the total mass.	
6	Ammonia	Hair Bleach	6% calculated as NH ₃		Above 2%; contains Ammonia
7	Oxalic acid its esters and alkaline salts	Hair care products	5%		For professional use only.
8	Chlorates of alkali metals	a) Toothpaste b) Other uses	a) 5% b) 3%		
9	M and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted	Oxidizing colouring agents for hair dyeing a) general use b) professional use	10% calculated as free base		a) Can cause an allergic reaction. Sensitivity test advisable before use. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows.

	derivatives of o-phenylenediamines (1) (m and o-diaminobenzene)				b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Sensitivity test advisable before use.
10	Methylphenyldiamines, their N-substituted derivatives and their salts (1) with the exception of 4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine	Oxidizing colouring agents for hair dyeing a) general use b) professional use	10% calculated as free base		a) Can cause an allergic reaction. Sensitivity test advisable before use. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows. b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Sensitivity test advisable before use.
11	2,4-diaminophenol (1) (Diaminophenols)	Oxidizing colouring agents for hair dyeing a) general use b) professional use	10% calculated as free base		a) Can cause an allergic reaction. Sensitivity test advisable before use. Contains diaminophenols. Do not use to dye eyelashes or eyebrows. b) For professional use only. Contains diaminophenols. Can cause an allergic reaction. Sensitivity test advisable before use.
12	Hydrogen Peroxide & other components or mixtures that release hydrogen peroxide including carbamide & zinc peroxide	a) Hair care products b) Skin-care preparations c) Nail hardening preparations d) Oral Hygiene Products	a) 12% H2O2 (40 vol.) b) 4% of H2O2 c) 2% H2O2 d) 0.1% of H2O2		(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	Formaldehyde (Formalin)	Nail Hardeners	5% calculated as formaldehyde		Protect cuticles with grease or oil.
14	Hydroquinone (1) (p-Hydroxyphenol)	(a) Oxidizing colouring agent for hair-dyeing 1) general use 2) professional use	2%		(a) 1. Do not use to dye eyelashes or eyebrows. Rinse the eyes immediately if product comes into contact with them. 2. For professional use only. Contains Hydroquinone. Rinse the eyes immediately if product comes into contact with them.
15	Potassium or sodium hydroxide (Caustic potash or caustic soda)	(a) Nail Cuticle Solvent (b) Hair Straightener 1) general use 2) professional use c) pH adjuster - depilatories d) other uses as pH adjuster	a) 5% by weight (3) 1) 2% by weight (3) 2) 4.5% by weight (3) (c) up to pH 12.7 (d) up to pH 11		(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children. (b) 1. Contains alkali. Avoid contact with eyes. Can cause blindness. 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.

16	Alpha-naphthol (1-naphthol)	Colouring agent for hair dyeing	0.5%		Contains alpha-naphthol
17	Phenol and its alkali salts (Carbolic acid)	Soaps and shampoos	1% calculated as phenol		Contains phenol
18	Pryogallol (1) (1,2,3-Benzenetriol)	Oxidizing colouring agent for hair dyeing (a) general use (b) professional use	5%		(a) Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains pyrogallol. (b) For professional use only. Contains pyrogallol. Rinse eyes immediately if product comes into contact with them.
19	Resorcinol (1) (1,3-Benzenediol)	(a) Oxidizing colouring agent for hair dyeing 1. general use 2. professional use 3. (b) Hair lotions and shampoos (c) Skin care	(a) 5% (b) 0.5% (c) 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. Rinse immediately if product comes in contact with them. (b)(c) Contains resorcinol.
20	(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.
21	Water-soluble zinc salts with the exception of zinc 4-hydroxybenzene sulphonate and zinc pyrithione		1% calculated as zinc		
22	Zinc 4-hydroxybenzene sulphonate (Zinc paraphenol sulphnate)	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		Avoid contact with eyes.
23	Ammonium monofluorophosphate	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds allowed total F concentration must not exceed 0.15%		Contains ammonium monofluorophosphate
24	Sodium monofluorophosphate	Ditto	0.15% Ditto		Contains sodium monofluorophosphate
25	Potassium monofluorophosphate	Ditto	0.15% Ditto		Contains potassium monofluorophosphate
26	Calcium monofluorophosphate	Ditto	0.15% Ditto		Contains calcium monofluorophosphate
27	Calcium fluoride	Ditto	0.15% Ditto		Contains Calcium fluoride
28	Sodium fluoride	Ditto	0.15% Ditto		Contains Sodium fluoride
29	Potassium fluoride	Ditto	0.15% Ditto		Contains Potassium fluoride
30	Ammonium fluoride	Ditto	0.15% Ditto		Contains Ammonium fluoride
31	Aluminum	Ditto	0.15% Ditto		Contains Aluminum fluoride

	fluoride				
32	Stannous fluoride	Ditto	0.15% Ditto		Contains Stannous fluoride
33	Hexadecyl ammonium fluoride	Ditto	0.15% Ditto		Contains Hexadecyl ammonium fluoride
34	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride	Ditto	0.15% Ditto		Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride
35	NN'N'-Tris (polyoxyethylene-N-hexadecyl-propylenediamine dihydro-fluoride	Ditto	0.15% Ditto		Contains NN'N'-Tris (polyoxyethylene-N-hexadecyl-propylenediamine dihydro-fluoride
36	Octadecenyl-ammonium fluoride	Ditto	0.15% Ditto		Contains Octadecenyl-ammonium fluoride
37	Sodium fluorosilicate	Ditto	0.15% Ditto		Contains Sodium fluorosilicate
38	Potassium fluorosilicate	Ditto	0.15% Ditto		Contains Potassium fluorosilicate
39	Ammonium fluorosilicate	Ditto	0.15% Ditto		Contains Ammonium fluorosilicate
40	Magnesium fluorosilicate	Ditto	0.15% Ditto		Contains Magnesium fluorosilicate
41	1,3-Bis (hydroxymethyl) imidazolidine-2-thione	a) Hair care preparations. b) Nail care preparations.	a) up to 2% b) up to 2%		Contains 1,3-Bis (hydroxymethyl) imidazolidine-2-thione
42	Benzyl alcohol	Solvents, perfumes and flavourings			
43	Nicomethanol hydro-fluoride	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds allowed total F concentration must not exceed 0.15%		Contains nicomethanol hydrofluoride
44	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.
45	Selenium disulphide	Anti-dandruff shampoos	1%		- Contains selenium disulphide. - Avoid contact with eyes or damaged skin.
46	Aluminium chloride (aluminum chloride hexahydrate)	Anti-perspirant	15% or less calculated as the hexahydrate form in aqueous solution		Some users of the product will experience skin irritation. Apply to skin of underarm. Not to be used generally over the body.
47	Aluminum chlorhydrate (chlorhydrol)	Ditto	25%		Do not apply to broken skin. If rash develops, discontinue use. Apply to skin of underarm. Not to be used generally over the body.
48	Triclosan (Irgasan DP-300)	Deodorant Toothpast	2% 0.5%	Irgasan DP300 is not to be formulated in feminine hygiene products	
49	Zinc phenolcarbonate	Deodorate	2%		
50	Quaternary ammonium compounds				

	a) Cetylpyridinium chloride b) Benzethonium chloride c) Benzalkonium chloride d) Alkyl (C12-C22) trimethyl ammonium chloride	Feminine wash Feminine wash Feminine wash Feminine wash	0.1% 0.1% 0.5% 0.1%		
51	1-(4chlorophenoxy)-1-(imidazol-1-yl)3,3-dimethylbuten-2-one (Climbazole)	Hair Shampoo			For external use only. Avoid contact with eyes if contact with eyes, rinse thoroughly with water. If irritation persists consult a physician.
52	Trichlorocarbanilide (TCC)	Deodorant	2%		
53	Pyrrithione Zinc (Zinc Pyrithione) (Zinc Omadine)	a) hairgroom preparation b) hair shampoo	a) 0.25%	a) Leave-on products only.	a) apply a small amount to scalp daily. a) & b) for external use only. Avoid contact with eyes. If contact with eyes, rinse with water. If irritation persists consult a physician.
54	Aluminum zirconium chloride hydroxide complexes $Al_xZr_yCl_z$ and the aluminum zirconium chloride hydroxide glycine complexes	Anti-perspirants	20% as anhydrous aluminum zirconium chloride hydroxide 5.4% as zirconium	1) the ratio of the number of aluminum atoms to that of zirconium atoms must be between 20 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 damages or broken skin.
55	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	a) stabilizer for hydrogen peroxide in rinse-off hair-care preparations. b) Non rinse-off hair care preparations	a)0.3% calculated as base 0.03% calculated as base		
56	1-hydroxy-ethylidene-diphosphonic acid & its salts (etidronic acid & its salts)	Hair-care	1.5% expressed as etidronic acid		
57	Lead acetate	Only for hair dyeing	0.6% cakcykated as kead		-keep away from children -avoid contact with eyes -wash hands after use contains lead acetate. Do not use to dye eyelashes, eyebrows, moustache. -if irritation develops, discontinue use
58	Magnesium fluoride	Oral hygiene products	0.15% calculated as F. When mixed with other allowed fluorine compounds total F concentration must not exceed 0.15%		Contains magnesium fluoride
59	Piroctone Olamine (Octopirox)	Antidandruff Shampoo/conditioners	1.0%		-for external only -avoid contact with eyes -if irritation persists, contact

					a physician
60	6-methylcoumarin	Oral hygiene products	0.003%		
61	Strontium Chloride hexahydrate	Toothpaste	3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.4%		-contains strontium chloride -frequent use by children is not advisable
62	Strontium acetate hexahydrate	Toothpaste	3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.4%		-contains strontium chloride -frequent use by children is not advisable
63	Hydrated Magnesium Silicate (Talc)	a) powdery products intended to be used for children under 3 years of age b) other products			Powder products: Keep powder away from baby's nose and mouth.
64	Trialkanolamines	a) non-rinse off products b) other products	a) 2.5%	a) b) -Do not use with nitrosating systems -Minimum purity: 99% -Maximum secondary alkanolamine content: 0.5% (concerns raw materials) -Maximum N-nitrosodi-alkanolamine content, 500g/kg -Keep in Nitrate-Free containers	
65	Fatty Acid dialkanolamides		Maximum dialkanolamine content 0.5%	-Do not use with nitrosating systems -Minimum purity: 99% -Maximum dialkanolamine content: 5% (concerns raw materials) -Maximum N-nitrosodi-alkanolamine content, 500g/kg -Keep in Nitrate-Free containers	
66	Monoalkanolamines		Maximum dialkanolamine content: 0.5%	-Do not use with nitrosating systems -Minimum purity: 99% -Maximum secondary alkanolamine content: 0.5% (concerns raw materials) -Maximum N-nitrosodi-alkanolamine content, 500g/kg -Keep in Nitrate-Free containers	
67	Salicylic Acid	Skin Care	<2.0%		1. Not to be used by children under 3 yrs. of age. 2. Not to be used in large portion of the body. 3. Not to be used for

					prolonged period of time.
68	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 eyes
69	Strontium Peroxide	-Rinse off hair care preparations -professional use	4.5% calculated as strontium in ready for use preparation	All products must meet the hydrogen peroxide requirements	-avoid contact with eyes -rinse eyes immediately if product comes in contact with them -for professional use only -wear suitable gloves

- 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 authorized does not exceed 1.
Only if the concentration exceeds 0.05%.

TABLE II - LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

Ref. No.	Substance	Maximum allowable concentration	Limitation and requirements	Conditions of use and warning which must be printed on the label
1	Benzenecarboxylic acid, its salts and esters (Benzoic acid, its salts and esters)	0.5% (acid)		
2	Propionic acid and its salt	2% (acid)		
3	2-Hydroxybenzoic acid and its salts (Salicylic acid and its salts)	0.5% (acid)	Not to be used in preparations for children under 3 years of age, except for shampoos	Not to be used for children under 3 years of age (1)
4	Hexa-2, 4-dianoic acid and its salts (Sorbic acid and its salts)	0.6% (acid)		
5	Formaldehyde and para-formaldehyde	0.2% (except for products for oral hygiene) 0.1% (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
6	Biphenyl-2-ol and its salts (o-phenyl phenol)	0.2% expressed as the phenol		
7	Zinc Pyrithione (Zinc Omadine)	0.5%	Authorized in rinsed off products. Forbidden in products for oral hygiene.	
8	Inorganic sulphites and hydrogensulphites	0.2% expressed as free SO ₂		
9	Sodium iodate	0.1%	Rinse-off products only	
10	Chlorobutanol (INN)	0.5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
11	4-hydroxybenzoic acid and its salts and esters (p-hydroxybenzoic acid)	0.4% (acid) for ester, 0.8% (acid) for mixtures of esters		
12	3-Acetyl-6-methylpyran-2,4(3H)-dione and its salts (Dehydroacetic acid)	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
13	Formic acid	0.5% (acid)		
14	3,3-Dibromo-4,4-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		
15	Under-10-enoic acid and salts (Undecylenic acid)	0.2%(acid)		
16	Hexetidine (INN)	0.1%		
17	5-Bromo-5-nitro-1,3 dioxane (Bronidox L)	0.1%	Rinse-off products only. Avoid formation of nitrosamines	
18	2-Bromo-2-nitro-1, 3-propanediol (Bronopol)	0.1%	Avoid formation of nitrosamines	
19	2, 4-Dichlorobenzyl alcohol	0.15%		
20	3,4,4'-Trichlorocarbanilide (Triclocarban)	0.2%	Purity criteria: 3,3',4,4'-Tetrachloro-azobenzene less than	

			1 ppm 3,3',4,4'-Tetra- chloroazoxybenzene less than 1 ppm.	
21	4-chloro-m-cresol (Chlorocresol)	0.2%	Prohibited in products intended to come into contact with mucus membranes	
22	Triclosan (INN) (Irgasan DP-300)	0.3%		
23	4-Chloro-3,5-xyleneol Triclosan (INN) (Irgasan DP-300)	0.5% 0.35		
24	3,3-Bis (1-hydroxymethyl- 2.5 dioximidazolidin-4-yl)- 1,1' methylenediurea ("Imidazolidinyl urea")	0.6%		
25	Poly(1-hexamethylenebi- guanide hydrochloride	0.3%		
26	2-Phenoxyethanol	1%		
27	Hexamethylenetetramine (methenamine) (INN)	0.15%		
28	Methenamine 3chloroallylo- chloride (INNM) (Quaternium 15)	0.2%		
29	1-(4-Chlorophenoxy)-1- (imidazol-1-yl) 3,3- diamethylbutan-2-one (Climbazole)	0.5%		
30	1,3-Bis(hydroxymethyl)-5,5- dimethylimidazolidine-2,4- dione	0.6%		
31	Benzyl alcohol	1%		
32	1-hydroxyl-4-methyl- 6(2,4,4-trimethylpentyl) 2- pyridon and its monoethanolamine salt (Piroctone Olamine), Octopirox)	1% 0.5%	For rinsed off products For other products	
33	6,6-Dibromo-4, 4-dichloro- 2,3'-methylene-diphenol (Bromochlorophen)	0.1%		
34	4-Isopropyl-m-cresol	0.1%		
35	Mixture of 5-Chloro-2- methyl-isothiazol-3(2H)-one and 2-methylisothiazol- 3(2H)-one with magnesium chloride and magnesium nitrate (Kathon CG)	0.0015% (of a mixture in the ratio 3 1 of 5- chloro-2- methylisothia zol 3 (2H) one & 2- methylisothia zol-3 (2H) one) Kathon CG		
36	2-benzyl-4-chlorophenol (Chlorophene)	0.2%		
37	2-Chloroacetamide	0.3%		Contains chloroacetamide
38	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	0.3% expressed as chlorhexidine		
39	1-Phenoxypropan-2-ol	1.0%	Only for rinse-off products	
40	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride	0.1%		
41	4,4-dimethyl-1,3- oxazolidine	0.1%	The pH of the finished product must not be lower	

	(Dimethyloxazolidine)		than 6	
42	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-hydromethyl) urea Idiazolidinyl Urea)	0.5%		
43	Butylated hydroxyanisole	0.2%	For products rinsed off after use	
44	Hexamidine (INN) & its salts including Isethionate & 4-hydroxy benzoate	0.1		
45	N-(trichloromethylthio)-cyclohex-4-ene-1,2-dicarboximide (Captan ISO)	0.5%	Do not use with lime or other strong alkali	
46	Chloro-N-(hydroxymethyl) acetamide	0.3% for the chloro-acetamide	For products rinsed off after use	
47	Phenonip	1%		
48	Cetyl pyridinium chloride	0.01-0.05%	For products that come in contact with the mucous membrane	
		0.01-1%	Other products	

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

TABLE III - LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

REF. NO.	SUBSTANCE	MAXIMUM ALLOWABLE CONCENTRATION	LIMITATIONS AND REQUIREMENTS	CONDITIONS OF USE AND WARNING WHICH MUST BE PRINTED ON THE LABEL	ALLOWED UNTIL
1	Chlorphenesin (INN)	0.30%			12-31-97
2	Benzethonium chloride (INN)	0.10%	Only for deodorant, hair care products and after shave products. Prohibited in the products intended to come into contact with mucous membrane		12-31-97
3	Benzalkonium chloride (INN), bromide and saccharinate	0.10%			12-31-97
4	Benzylhemiformal				12-31-97
5	3-Iodo-2-propynylbutyl carbamate		For rinse-off products only		12-31-97
6	Sodium hydroxymethyl aminoacetate	0.10%			12-31-97

TABLE IV - NON-PERMISSIBLE COLORS IN COSMETIC PREPARATION

REF. NO	FD & C Designation	Color Index Number	Common Name
1	FD & C Green No. 1	CL 42085	Guinea Green B
2	FD & C Green No. 2	CL 42095	Light Green SF Yellowish
3	FD & C Red No. 1	CL 16155	Ponceau 3R
4	FD & C Violet No. 1		Wool Violet 4BN
5	D & C Blue No. 7	CL 42052	Patent Blue NA
6	D & C Red No. 5	CL 16150	Ponceau 2R
7	D & C Red No. 10	CL 15630	Lithol Red
8	D & C Red No. 11		Lithol Red CA
9	D & C Red No. 12		Lithol Red BA
10	D & C Red No. 13		Lithol Red SR
11	D & C Red No. 14	CL 15500	Lake Red D
12	D & C Red No. 18	CL 26125	Oil Red OS
13	D & C Red No. 24	CL 45366	Tetrachlorofluorescein
14	D & C Red No. 29	CL 45457	Bluish Orange TR
15	D & C Red No. 35	CL 12120	Toluidine Red
16	D & C Red No. 37	CL 45170:3	Rhodamine B Stearate
17	D & C Red No. 38	CL 12350	Toluidine Maroon
18	D & C Orange No. 8	CL 45365	Dichlorofluorescein
19	D & C Orange No. 14	CL 45456	Orange TR
20	D & C Orange No. 16	CL 45371	Diiododibromofluorescein
21	Ext. D & C Blue No. 1	CL 52015	Methylene Blue
22	Ext. D & C Blue No. 4	CL 63010	Atizarin Saphirol
23	Ext. D & C Green No.1	CL 10020	Naphthol Green B
24		CL 18055	Amidonaphthol Red 6 B
25	Ext. D & C Red No. 2	CL 16105	Pigment Scarlet NA
26	Ext. D & C Red No. 3	CL 45109	Violamine R
27	Ext. D & C Red No. 14	CL 12140	Oil Red XO
28	Ext. D & C Red No. 15	CL 16155	Ponceau 3 R
29	Ext. D & C Orange No. 3	CL 14600	Orange I
30	Ext. D & C Yellow No. 1	CL 13065	Metanil Yellow

31	Ext. D & C Yellow No. 6	CL 14010	Dupont Yellow
32	Ext. D & C Yellow No. 9	CL 11380	Yellow AB
33	Ext. D & C Yellow No. 10	CL 11390	Yellow OB Graphite
34		CL 77266	Carbon Black (prepared by 'impingement or channel process) Pigment Black 6/7 Permatone Orange
35	D & C Orange No. 17	CL 12075	
36	D & C Red No. 8	CL 15585	Lake Red C
37	D & C Red No. 9	CL 15581:1	Lake Red CBA
38	D & C Red No. 19	CL 45170	Rhodamine
39		CL 26105	
40		CL 42555-1	
41		CL 42555-2	
42		CL 42535	
43		CL 61544	
44	D & C Red No. 33 Zirconium Lake	CL 17200	Food Red 12

**TABLE V - PERMISSIBLE COLOR ADDITIVES
LIST OF COLORANT RESTRICTED/ALLOWED FOR COSMETIC PRODUCTS**

The following color additives are not to be incorporated in cosmetics for use in the area around in the eye.

REF NO	FD & C Designation	Color Index Number	Common Name	Uses and Restrictions
1	F D & C Green No. 3	CL 42053	Fast Green FCF	To color externally applied cosmetics
2	F D & C Red No. 4	CL 14700	Ponceau SX	- do -
3	F D & C Yellow No. 6	CL 15985	Sunset Yellow	- do -
4	D & C Blue No. 4	CL 42090	Alphazunne PG	to color externally applied cosmetics
5	D & C Brown No. 1	CL 20170	Resorcin Brown	to color externally applied cosmetics
6	D & C Green No. 6	CL 61565	Quinizarine Green SS	- do -
7	D & C Green No. 8	CL 59040	Pyranine	to color externally applied cosmetics
8	D & C Orange No. 4	CL 15510	Orange II	to color externally applied cosmetics
9	D & C Orange No. 5	CL 45370:1	Dibromofluorescein	in amount not exceeding 0.01% by weight of the finished product to color externally applied cosmetics
10	D & C Orange No. 10	CL 45425:1	Diiodofluorescein	to color mouthwashes & dentitrics that are ingested cosmetics; to color lipstick and other lip cosmetics in amounts to exceeding 5% by weight of the finished product to color externally applied cosmetics
11	D & C Orange No. 11	CL 45425	Erythrosine Yellowish NA	
12	D & C Red No. 6	CL 15850	Pigment Rubine	
13	D & C Red No. 7	CL 15850:1	Lithol Rubine BCA	to color externally applied cosmetics
14	D & C Red No. 17	CL 26100	Sudan III	- do -
15	D & C Red No. 21	CL 45380:2	Tetrabromofluorescein	to color cosmetics generally
16	D & C Red No. 22	CL 45380	Eosin YS	- do -
17	D & C Red No. 27	CL 45410:1	Tetrachlorotetrabromofluorescein	to color externally applied cosmetics
18	D & C Red No. 28	CL 45410	Phloxine B	to color cosmetics generally
19	D & C Red No. 30	CL 73360	Helindone Pink CH or VAT Red I	to color cosmetics generally
20	D & C Red No. 31	CL 15800	Brilliant Lake Red	- do -
21	D & C Red No. 33 except	CL 17200		

	its Zr lake		Fast Acid Magenta	- do - - do -
22	D & C Red No. 34	CL 15880	Deep Maroon; Fachon Maroon	to color externally applied cosmetics
23	D & C Red No. 36	CL 12085	Chlorinated p-Nitroaniline Red	to color lipsticks and other lip cosmetics in amount not exceeding 3% expressed as pure dye by weight of each lipstick or other lip cosmetics, to color mouthwashes and dentrifices.
24	D & C Violet No. 2	CL 60725	Alizurol Purple SS	to color externally applied cosmetics
25	D & C Yellow No. 7	CL 45350	Fluorescein	
26	D & C Yellow No. 8	CL 45350	Uranine	to color lipsticks and other lip cosmetics in amount not exceeding 3% expressed as pure dye by weight of each lipstick or other lip cosmetics; to color mouthwashes and dentrifices.
27	D & C Yellow No. 10	CL 47005	Quinoline Yellow WS	
28	D & C Yellow No. 11	CL 47000	Quinoline Yellow	
29	Ext. D & C Yellow No. 7	CL 10316	Naphthol Yellow	to color externally applied cosmetics
30	Ext. D & C Yellow No. 2	CL 60730	Alizurol Purple	to color externally applied cosmetics - do - to color cosmetics generally to color externally applied cosmetics - do - - do -

The following color additives may be incorporated in cosmetics for use in the are around the eye.

REF NO	FD & C Designation	Color Index Number	Common Name	Uses and Restrictions
31	FD & C Blue No. 1 and its Aluminum Lake	CL 42090	Brilliant Blue FCF	To color cosmetics generally including those applied in the area of the eye
32	FD & C Red No. 40 and its Aluminum Lake	CL 46035	Allura Red	- do -
33	FD & C Yellow No. 5 and its Aluminum Lake	CL 19140	Tartrazine	- do -

34	D & C Green No. 5 and its Aluminum Lake	CL 61570	Alizarin Cyanide Green F	- do -
35		CL 75120	Annato	to color cosmetics, including those intended for use in the area of the eye
36		CL 75470	Carmine	- do -
37		CL 75130 (CL 40800)	B-Carotene	- do -
38		CL 75130	Bismuth Citrate	used in cosmetics intended for coloring hair on scalp & subject to the following restrictions; 1) the amount of Bismuth Citrate in the cosmetic shall not exceed 0.5% (weight per volume), 2) the cosmetic may not be used to color eyelashes, eyebrows or hair on parts to the body other than the scalp
39		CL 75810	Disodium EDTA	
40		CL 75810	Copper	to color shampoos only
			Potassium Sodium Copper Chlorophylline (chlorophyllin copper complex)	to color dentrifices subject to the following restrictions: 1) it shall not be used at a level in excess of 0.1%, 2) it may be used in combination with the following substances: a) water b) glycerine c) sodium carboxymethyl cellulose d) tetrasodium pyrophosphate e) sorbitol f) calcium carbonate g) calcium phosphate, dibasic h) magnesium phosphate, tribasic i) sodium N-lauryl sarcosinate j) artificial sweeteners that are generally recognized as safe.
41		CL 77400		k) Flavors that are generally recognized as safe l) Preservatives that are generally recognized as safe
42		CL 77400	Bronze Powder	
43	CL 77007	Copper Powder	To color cosmetics, including those applied to the area of the eye	
		Ultramarines	- do -	
44	CL 77742			
45	CL 77947	Manganese Violet Pigment Violet 16	to color externally applied cosmetics including those applied to the area of the eye	

46		CL 77510	Zinc Oxide	- do -
47		CL 77820	Ferric Ferrocyanide, Prussian Blue	- do -
48			Silver	- do -
49			Caramel	to color fingernail polish at a level not to exceed 1% by weight of the final product
			Lead Acetate	to color cosmetics generally including those applied to the area of the eye
				to color cosmetics intended for coloring hair subject to the following restrictions: 1) the amount of lead acetate shall be such that the lead content calculated as lead (Pb) shall not exceed 0.6% (weight per volume); 2) the label of the cosmetic shall bear the ff. Cautionary statement conspicuously displayed thereon: CAUTION: Contains lead acetate. For external use only. Keep out of reach of children. Do not use on cut or abraded scalp. If skin irritations, develop, discontinue use. Do not use to color moustaches, eyelashes, eyebrows or hair on parts of the body other than the scalp. Do not get into eyes. Follow instructions carefully and wash hands thoroughly after use.
50		CL 77163	Bismuth Oxychloride	
51				
52		CL 75480	Guaiazulene	
			Henna	To color cosmetics including those intended for use in the area of the eye
53		CL 77499		To color externally applied cosmetics
54		CL 77492	Black Iron Oxides	
55		CL 77491	Yellow Iron Oxides	To color hair only; it is not used in coloring eyelashes, eyebrows, or generally in the area of the eye. Label shall bear the following: "Do not use in cut or abraded scalp."
56		CL 77491	Red Iron Oxides	
57		CL 77520	Brown Iron Oxides	To color cosmetics including those intended for use in the area of the eye
			Ferric Ammonium Ferrocyanide	
58		CL 77289		- do -

59		CL 75170	Chromium Hydroxide Green	- do -
60		CL 77288	Guanine	- do -
61			Chromium Oxide Green	to color externally applied cosmetics including those intended for use in the area of the eye
62		CL 77019	Pyrophyllite	- do -
63		CL 77891	Mica	to color cosmetics generally
64		CL 77000	Titanium Dioxide	to color externally applied cosmetics including those intended for use in the area of the eye.
65			Aluminum Powder	to color externally applied cosmetics
			Dihydroxyacetone	to color cosmetics including those applied to the area of the eye
				- do -
				to color externally applied cosmetics including those intended for use in the area of the eye
				for use in externally applied cosmetics "intended solely or in part to impart color to the human body."

TABLE VI - LIST OF PROVISIONALLY ALLOWED COLORS IN COSMETIC PREPARATIONS

Ref. No.	Designation	Color Index No.	Common Name	User/Restrictions	Allowed Until
1	Acid red 195			3	6-30-98
2	Aluminum, Zinc, Magnesium and Calcium Stearate			1	6-30-98
3	Anthocyanin			1 E163	6-30-98
4	Beet Red			1 E162	6-30-98
5	Bromcresol Green			4	6-30-98
6	Bromthymol Blue			4	6-30-98
7	Capsanthin/Capsorubin			1 E160C	6-30-98
8	Lactoflavin/Riboflavin			1 E101	6-30-98
9		CL 10006	Pigment Green	4	6-30-98
10	Ext. DC Yellow No. 5	CI 11680	Hansa Yellow	3	6-30-98
11		CI 11710	Hansa Yellow	3	6-30-98
12	Ext. DC Orange No. 1	CI 11725	10G	4	6-30-98
13		CI 11920	Nansa Orange	1	6-30-98
14		CI 12010	Sudan Orange G	3	6-30-98
15	Ext. DC Orange No. 4	CI 12120	Fat Brown R	4	6-30-98
16		CI 12370	Orange SS	4	6-30-98
17		CI 12420	Permanent Red FGR	4	6-30-98
18		CI 12480	Permanent Red F4RH	4	6-30-98
19		CI 12490	Permanent Brown FG	1	6-30-98
20		CI 12700	Permanent Carmine FB	4	6-30-98
21		CI 13015	Sudan Yellow	1	6-30-98
22		CI 14270	3G	1 E 013	6-30-98
23	Ext. DC Red No. 10	CI 14720	Fast Yellow SX	1 E122	6-30-98
24		CI 14720	Chrysoine S	1 E122	6-30-98
25		CI 14815	Carmoisine	1 E125	6-30-98
26		CI 15525	Chrysoine Scarlet GN	1	6-30-98
27		CI 15580	Permanent Red	1	6-30-98
28	Ext DC Red No. 8	CI 15620	Toner NCR	4	6-30-98
29		CI 15865(3)	Helio Red RMT	1	6-30-98
30		CI 15980	Fast Red S	1 e111	6-30-98
31	FDC Red No. 2	CI 16185	Pigment Red 48	1 e123	6-30-98
32	DC Orange No. 3	CI 16230	Orange GN	3	6-30-98
33		CI 16255(3)	Amaranth	1 e124	6-30-98
34		CI 16290	Orange G	1 e126	6-30-98
35	Ext DC Red No. 11	CI 18050	Ponceau 4R	3	6-30-98
36		CI 18130	Ponceau6R	4	6-30-98
37		CI 18690	Guanine2G	4	6-30-98
38		CI 18736	Fast Red 3BL	4	6-30-98
39	Ext. DC Yellow No. 3	CI 18820	Yellow NR	4	6-30-98
40		CI 18965	Red RC	1	6-30-98
41		CI 12150	Fast Light Yello	1	6-30-98
42		CI 20040	Yellow 2G	4 Max. 2,2'-dimethylbenzidine concentration in the coloring agent 5ppm	6-30-98
			Sudan Red G		
			Permanent Yellow NGG		
43	DC Black No. 1	CI 20470		4	6-30-98
44		CI 21100		4 Max. 3,3'-	6-30-98

45	Ext Dc Red No. 13	CI 21108 CI 21230	Naphthol Blue Black	dimethyl-benzidine	6-30-98				
46				Vulcan Fast Yellow GR		concentration in the coloring agent 5ppm			
47				Pigment Yellow 83		4 -do-			
48				Sudan Yellow GRN		3			
49				Fast Red BR		4			
50				Croceine Scarlet		4			
51				MOO		4			
52				Black 7984		1 E152			
53				Black PN		1 E151			
54				Orange 2G		4			
55				b-Apo-8'-carotinal		1 E160 E			
56				b-Apo-8'-carotenoic acid,		1 E161 F			
57				ethyl ester		4			
58				Canthaxatine		4			
59				Patent Blue VF		3			
60				Patent Blue V		4/5 pmm max.			
61				Fast Acid Green B		concentration in the finished product			
62				Neptune Green SGX		3			
63				Acilan Fast		3			
64				Green 10G		1 E142			
65				Fuchsine		4			
66				Brilliant Wool Blue FFR		4			
67				Wool Green BS		4			
68				Acid Red 52		1 when used in lipstick the colouring agent is allowed only in free acid for and in a max. concentration of 1%			
				Acid Violet 9		2 Not more than 1% 2-(6-hydroxy-3-OXO-3H-xanthen-9-yl) benzoic acid & 2% 2-(bromo-6-hydroxy-3OXO-3H-xanthen-9-yl) benzoic acid			
				Acid Red 50		3			
				Solvent Orange 16		1 E127, -do-			
				Phloxine		4			
69			FDC Red No. 3	CI 44045 CI 45430(3) CI 50325 CI 50420 CI 51319 CI 58000 CI 60724 CI 61585			3	6-30-98	
70								4	6-30-98
71								3	6-30-98
72								4	6-30-98
73								1	6-30-98
74								4	6-30-98
75								4	6-30-98
76								4	6-30-98

77		CI 62045	Nigrosine Pigment Violet 23	4	6-30-98
78		CI 69800	Alizarin Violet B	1 E130	6-30-98
79		CI 69825	Alizarin Blue	1	6-30-98
80		CI 71105	Alizarin Sky Blue	3	6-30-98
81	DC Blue No. 6	CI 73000	R	1	6-30-98
82	FDC Blue No. 2	CI 73015	Indanthrene	1 E132	6-30-98
83		CI 73385	Blue RS	1	6-30-98
84		CI 73900	Indanthrene	4	6-30-98
85		CI 73915	Blue BC	4	6-30-98
86		CI 74100	Pigment Orange	4	6-30-98
87		CI 74160	43	4	6-30-98
88		CI 74180	Indigo	1	6-30-98
89		CI 74260	Indigotine	4	6-30-98
90		CI 75100	Pigment Violet	2 E 160 d	6-30-98
91		CI 75125	36	1	6-30-98
92		CI 75135	Quinacridone	1	6-30-98
93		CI 75300	Violet 19	1 E161 d	6-30-98
94		CI 77002	Pigment Red 122	1 E100	6-30-98
95		CI 77004	Heliogen Blue G	1	6-30-98
96		CI 77015	Heliogen Blue B Sulf. Phthlo.	1	6-30-98
97		CI 77120	Blue	1	6-30-98
98		CI 77220	Heliogen Green	1 E170	6-30-98
99		CI 77231	G	1	6-30-98
100		CI 77267	Crocetin	1	6-30-98
101		CI 77268.1	Lycopene	1 E153	6-30-98
102		CI 77346	Rubixanthin Curcumin	1	6-30-98
103		CI 77480	Aluminum	1 E175	6-30-98
104		CI 77489	Hydroxide	1 E172	6-30-98
105		CI 77713	Kaolin Pigment Red	1	6-30-98
106		CI 77745	101/102 Barium Sulfate Calcium Carbonate Calcium Sulfate Pigment Black 9 Pigment Black 8 Pigment Blue 28/ Pigment 14 Ferrous Oxide Magnesium Carbonate Manganous Phosphate	1	6-30-98

Uses and Restrictions:

1. Coloring agents which are permitted for all cosmetics goods.
2. Coloring agents which are permitted for all cosmetics goods, with the exception of eye area preparations.
3. Coloring agents which may only be used in cosmetic goods that do not come into contact with mucosa.

4. Coloring agents which may only be used in cosmetic goods intended to come into contact with the skin only briefly.

- (1) Lakes or salts of these colouring agents using substances not prohibited under Table IX and strontium compounds except those listed in Table IX, are equally allowed.
- (2) Coloring Agents whose number is preceded by the letter "E" in accordance with the EEC directive of 1962 concerning foodstuffs and coloring matters must fulfill the purity laid down in those directives.
- (3) The insoluble barium, strontium and zirconium lakes, salts and pigments of those colouring agents shall also be permitted, they must pass the test for insolubility which will be determined by the procedure laid down in Article 8.

Table VII
Sunscreen Agents
List of Sunscreen Agents which cosmetic products may contain

Sunscreens are substances which are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays.

These sunscreens may be added to other cosmetic products within the limits and under the conditions laid down in this table.

Other sunscreens used in cosmetic products solely for the purpose of protecting the products against UV rays are not included in this Table.

Ref. No.	Substance	Maximum Allowable Concentration	Limitations and requirements	Conditions of use and warning which must be printed on the label
1	N,N,N-trimethyl-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate (Camphor benzalkonium methosulfate)	15%		This term sunscreen. When used anywhere in the labelling of a cosmetic product. Must be qualified by the following to describe the cosmetic benefit provided by the sunscreen: "This product contains a sunscreen that assists in protecting the (site of action) from damage by the sun." Contains oxybenzone (1)
2	Homosalate (INN)	6%		
3	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts (Phenylbenzimidazole sulphonic acid)	15%		
4	3,3-(1,4-Phenylenedimethylidene) bis (7,7-dimethyl-2-oxo-bicyclo-(2,2,1) heptane-1-methane-sulphonic acid) and its salts (Terephthalidene dicamphor sulfonic acid)	8% (expressed as acid)		
5	1-(4-ter-butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione (Butyl methoxydibenzoyl methane) (Parsol 1789)	10% (expressed as acid)	Prohibited in aerosols (sprays)	
6	Oxybenzone (INN)	5%		
7	(2-Hydroxy-4-methoxybenzophenone) (Benzophenone-3)	10%		
8	2-Ethoxyethyl-p-methoxycinnamate (Cinoxate)	3%		
9	Diethanolamine methoxycinnamate (DEA methoxycinnamate)	10%		
10	Digalloyl tnoleate	5%		
11	Dioxybenzone (Benzophenone08)	3%		
12	Ethyl 4-[bis(hydroxypropyl)] aminobenzoate (Ethyl dihydroxypropyl PABA)			
13	Glyceryl aminobenzoate (Glyceryl PABA)			
14	Lewsone / dihydroxyacelone			
15	Menthyl entranilate			
16	Octocrylene			
17	Red perolatum			
18	Titanium dioxide			
19	Trolamine salicylate			
20	2-Ethylhexyl 4-dimethylaminobenzoate (Octyl dimethyl PABA)			
21	2-Ethylhexyl 4-methoxycinnamate (Octyl methoxycinnamate)			
22	Zinc Oxide			

(1) Not required if concentration is 0.5% or less and when it is used for product protection purpose.

**TABLE VIII
LIST OF SUNSCREEN AGENTS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN**

Ref. No.	Substance	Maximum Allowable Concentration	Limitations and Requirements	Conditions of use and Warning which must be printed on the label	Allowed Unit
1	Ethoxylated-ethy-4-amino benzoate (Ethoxylated-ethyl PABA)	10%		The term sunscreen when used anywhere in labelling of a cosmetic product must be qualified by the following to describe the cosmetic benefit provided by the sunscreen: "This product contains a sunscreen that assists in protecting the (site of action) from damage by the sun."	12-31-97
2	2-Ethylhexyl salicylate (Octyl salicylate)	5%			12-31-97
3	Isopentyl-4-methoxycinnamate (Mixed Isomers)	10%			12-31-97
4	2-Hydroxy-4-methoxybenzophenone 5 sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)	10%			12-31-97
5	3-(4' Methylbenzylidene)-d-1-camphor (4-Methylbenzylidene camphor)	6%			12-31-97
6	3-Benzylidene camphor	6%			12-31-97
7	4-Isopropyl-dibenzoyl-methane	5%			12-31-97
8	4-Isopropylbenzyl salicylate	4%			12-31-97
9	4-Isopropylbenzyl salicylate	5%			12-31-97
10	2,4,6 Trianilino-(p-carbo-2'-ethylhexyl-1'-oxil)-1,3,5-triazine	6% (expressed as acid)			12-31-97
11	Alpha-(2-Oxoborn-3-ylidone) Toluene-4-sulphonic acid and its salts (toluene sulfonic acid) (4-Methylbenzene sulfonic acid) 3-Imidazol-4-ylacrylic acid and its ethyl ester (Urocanic acid)	2% (expressed as acid)			12-31-97

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

1	N-5-Chlorobenzoxazol-2-ylacetamide
2	2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine and its salts)
3	Deanol aceglumate
4	Spirolactone
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	Anonitum 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 its salts
16	Alkyne alcohols, their esters, ethers and salts
17	Isoprenaline
18	Allyl isothiocyanate
19	Alloclamide and its salts
20	Nalorphine, its salts and ethers
21	Sympathicomimetic amines acting on the central nervous system: Any substance contained in the first list of medicaments which are subject to medical prescription.
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 and its galenical preparations
36	2,3-Dichloro-2-methylbutane
37	Substances with androgenic effect
38	Anthracene oil
39	Antibiotics
40	Antimony and its compounds
41	Apocynum cannabinum L. and its preparations
42	Apomorphine (R5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo (de,g)-quinoline-10,11-diol) and its salts
43	Arsenic and its compounds
44	Atropa belladonna L. and its preparations
45	Atropine, its salts and derivatives
46	Barius salts with the exception of barium sulphate, barium sulphide under the conditions laid down in Table 1 and lakes, salts and pigments prepared from the colouring agents in Table V
47	Benzene
48	Benzimidazol-2(3H)-one
49	Benzazepines and bezodiazepines
50	1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts
51	2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts

52	Isocarboxazid
53	Bendroflumethiazide and its derivatives
54	Beryllium and its compounds
55	Bromine, elemental
56	Bretylum tosilate
57	Carbromal
58	Bromisoval
59	Brompheniramine and its salts
60	Benzilonium bromide
61	Tetrylammonium bromide
62	Brucine
63	Tetracine and its salts
64	Mofebutazone
65	Tolbutamide
66	Carbutamide
67	Phenylbutazone
68	Cadmium and its compounds
69	Cantharides, <i>Cantharis vesicatoria</i>
70	(1R, 2S)-Hexahydro-,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
71	Phenprobamate
72	Nitroderivatives of carbazole
73	Carbon disulphide
74	Catalase
75	Cephaeline and its salts
76	<i>Chenopodium ambrosioides</i> (essential oil)
77	2,2,2-Trichloroethane-1,1-diol
78	Chlorine
79	Chlorpropamide
80	Diphenoxylate hydrochloride
81	4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82	Chlorzoxazone
83	2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)
84	Chlorprothixene and its salts
85	Clofenamide
86	N,N-bis (2-chloroethyl) methylamine N-oxide and its salts
87	Chlormethine and its salts
88	Cyclophosphamide and its salts
89	Mannomustine and its salts
90	Butanilcaine and its salts
91	Chlormezanone
92	Triparanol
93	2-(2-(4-Chlorophenyl)-2-phenylacetyl)indan 1,3-dione (chlorophacinone-ISO)
94	Chlorphenoxamine
95	Phenaglycodol
96	Chloroethane
97	Chromium; chromic acid and its salts
98	<i>Claviceps purpurea</i> Tul., its alkaloids and galenical preparations
99	<i>Conium maculatum</i> L. (fruit, powder, galenical preparations)
100	Glycyclamide
101	Cobalt benzenesulphonate
102	Colchicine, its salts and derivatives
103	Colchicoside and its derivatives
104	<i>Colchicum autumnale</i> L. and its galenical preparations
105	Convallatoxin
106	<i>Anamirta cocculus</i> L. (fruit)
107	<i>Croton tiglium</i> (oil)
108	1-Butyl-3-(n-crotonoylsulphanilyl) urea

109	Curare and curarine
110	Synthetic curarizants
111	Hydrogen cyanide and its salts
112	2- α -Cyclohexylbenzyl (N,N,N ¹ ,N ¹ -tetraethyl) trimethylenediamine
113	Cyclomenol and its salts
114	Sodium hexacyclonate
115	Hexapropymate
116	Dextropropoxyphene
117	O,O ¹ -Diacetyl-N-allyl-N-normorphine
118	Pipazetate and its salts
119	5-(α B-Dibromophenetyl)-5-methylhydrantoin
120	N,N ¹ -Pentamethylenebis (trimethylammonium) salts, e.g. Pentamethonium
121	N,N ¹ -((Methylimino)diethylene)bis(ethyl dimethylammonium) salts, e.g., azamethonium bromide
122	Cyclarbamate
123	Clofenotane; DDT (ISO)
124	N,N ¹ -Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*
125	Dichloroethanes (ethylene chlorides)
126	Dichloroethylenes (acetylene chlorides)
127	Lysergide and its salts
128	3-Diethylaminopropyl cinnamate
129	O,O ¹ -Diethyl 0-4nitrophenyl phosphorothiate (parathion-ISO)
130	(Oxalylbisiminoethylene)bis((o-chlorobenzyl)diethylammonium) salts, e.g., ambenonium chloride
131	Methylprylon and its salts
132	Digitaline and all heterosides of Digitalis purpurea L.
133	7-(2-Hydroxy-3-(2-hydroxyethyl)-N-methylamino)propyl)theophylline(xanthinol)
134	Dioxethedrin and its salts
135	Piprocuarium
136	Propyphenazone
137	Tetrabenazine and its salts
138	Propyphenazone
139	Tetrabenazine and its salts
140	Captodiame
141	Mefeclozazine and its salts
142	Dimethylamine
143	1,1-Bis(dimethylaminomethyl) propyl benzoate (amydricine, 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 salts
155	Sulfinpyrazone
156	N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e.g., isopropamide iodide
157	Benactyzine
158	Benzatropine and its salts
159	Cyclizine and its salts
160	5,5-Diphenyl-4-imidazolidone
161	Probenecid
162	Disulfiram; thiram (ISO)
163	Emetine, its salts and derivatives
164	Ephedrine and its salts
165	Oxanamide and its derivatives

166	Eserine or physostigmine and its salts
167	Esters of 4-aminobenzoic acid, with the free amino group, with the exception of ethoxylated ethyl-4-aminobenzoate and 2-ethylhexyl-4-dimethyl aminobenzoate
168	Choline sales 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	Bemegrade and its salts
184	Valnoctamide
185	Haloperidol
186	Paramethasone
187	Fluanisone
188	Tifluperidol
189	Fluoresone
190	Fluorouracil
191	Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Table 1
192	Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*
193	Galantamine
194	Progestogens
195	1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)(lindane)
196	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octa-hydro-1,4,5,8-dimethanonaphthalene (endrin-ISO)
197	Hexachloroethane
198	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,8,8a-hexahydro-1,4,5,8-dimethanonaphthalene (isodrin-ISO)
199	Hydrastine, hydrastanine 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	Demathylenebis (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	Alpha-santonin ((3S, 5aR, 9bS)-3,3a,4,5,5a,9b-hexahydro-3, 5a, 9-trimethyl-naphto (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
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--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 metilsulfate
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 nitrates, with the exception of sodium nitrite
249	Nitrobenzene
250	Nitrocresols and their alkali metal salts
251	Nitrofurantoin
252	Furazolidone
253	Propare-1,2,3-triyl trinitate
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	Pentaerithryl tetranite
266	Petrichloral
267	Octamylamine and its salts
268	Pecric acid
269	Penacemide
270	Defiencloxazine
271	2-Penhylinan-1,3-dione (phenindoine)
272	Ethylphenacemide
273	Phenprocoumon
274	Fenylramidol
275	Triamterence and its salts

276	Tetraethyl pyrophosphate (TEPP (IS0)
277	Tritolyl phosphate
278	Psilocybine
279	Phosphorus and metal phosphides
280	Thalidomide and its salts
281	Physostigma venenosum Balf
282	Picrotoxin
283	Pilocapine and its salts
284	Alpha-piperidin-2-ylbenzyl acetate laevorotatory threoform (levophacetoperane) and its salts
285	Pipradrol and its salts
286	Azacyclonol and its salts
287	Bietamiverine
288	Butopiprine and its salts
289	Lead and its compounds, with the exception of that mentioned in table 1#57 under the conditions state
290	Coniine
291	Prunus laurocerasus L. ('cherry laurel water')
292	Metyrapone
293	Radioactive substances
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 in table 1, #45
298	Solanum nigrum L. and its galenical preparations
299	Sparteine and its salts
300	Glucocorticoids
301	Datura strammium 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	Pilocapus jaborandi Holmes and its galenical preparations
312	Tellerium 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	Thevetia neriifolia Juss. Glycoside extract
322	Ethionamide
323	Phenothiazine and its compounds
324	Tranlycypromine and its salts
325	Trichloronitromethane (chloropicrine)
326	2,2,-Tribromoethanol (tribromoethyl alcohol)
327	Trichlormethine and its salts
328	Tretamine
329	Gallamine triethiodide
330	Urginea scilla Stern. And its galenical preparations

331	Veratrine, its salts and galenical preparations
332	Schoenocaulon officinale Lind. (seeds and galenical preparations)
333	Veratrum Spp. And their preparations
334	Vinyl chloride monomer
335	Ergocalciferol and chlorecalciferol (Vitamins D2 and D3)
336	Salts of O-alkyldithiocarbonic acids)
337	Yohimbine and its salts
338	Dimethyl sulfoxide
339	Diphenhydramine and its salts
340	4-tert-Butylphenol
341	4-tert-Butylpyrocatechol
342	Dihydrotachysterol
343	Dioxane
344	Morpholine and its salts
345	Pyrethrum album L. and its galenical preparations
346	2-(4-Methoxybenzyl-N-(2-pyridyl)amino)ethyl dimethylamine 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	Furo (3,2-g) chromen-7-one and its alkyl-substituted derivatives (e.g., trioxysalan and 8-methoxypsoralen), except for normal content in natural essences used
359	Oil from the seeds of Laurus nobilis L.
360	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'-dihydropyridone
362	3'-ethyl-5',6',7,8'-tetrahydro-5',6',8',8',-tetramethyl-2'-acetonaphthalene (acetyl ethyl tetramethyltetralin, AETT)
363	o-phenylenediamine and its salts
364	4- methyl-m-phenylenediamine and its salts
365	Aristolochic acid and its salts
366	Chloroform
367	2,3,7,8,-Tetrachlorodibenzo-p-dioxin
368	2,6-Dimethyl-1,3-dioxan-4-ylacetate (Dimethoxane)
369	Pyrithione sodium (INNM)
370	2,2'-Dihydroxy-3,3',5,5',6,6'--hexachlorodiphenylmethane (Hexachlorophene)
371	6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (Minoxidil) and its salts and derivatives
372	3,4',5-Tribromosalicylanilide (Tribromsalan)
373	Phytolacca Spp. And their preparations
374	Tretinoin (retinoic acid and its salts)
375	1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole-CI 76050) & their salts
376	4-Methoxy-m-phenylenediamine (2,4-diaminoanisole) and their sulfate 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	Benzoyl peroxide
383	2-Amino-4-nitrophenol
384	2-Amino-5-nitrophenol
385	11- α -Hydroxypregn-4-ene-3,20-dione and its esters
386	Colouring agent CI 42640
387	Colouring agent CI 13065
388	Colouring agent CI 42535
389	Colouring agent CI 61554
390	Antiandrogens with steroid structure
391	Zirconium and its compounds, with the exception of the complexes under table 1 and of zirconium lakes, salts and pigments of colouring agents listed in table V and VI
392	Thyrothricine
393	Acetonitrile
394	Tetrahydrozoline and its salts
395	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in table 1
396	Dithio-2,2'-bispyridine-dioxide 1,1' (additive with the trihydrated magnesium)
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	Methanol
410	Nitrosamines
411	Secondary dialkanolamines
412	4-Amino-2-nitrophenol
413	2-Methyl-m-phenylenediamine