

SCHEDULE 6

Regulations 5(2) and 7(2)

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTIONS

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

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

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

In this Schedule—

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

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

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

All preservative substances containing formaldehyde or any substances named in this Schedule which release formaldehyde must be labelled with the warning “contains formaldehyde” when the concentration of formaldehyde in the final product exceeds 0.05 per cent.

Names which appear in square brackets in column 2 of this Schedule are the INCI names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision [96/335/EC](#)(1).

(1) O.J. No. L132, 1.6.96, p.1.

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PART I

PRESERVATIVES LISTED IN ANNEX VI, PART 1 OF THE DIRECTIVE AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>	
1	Benzoic acid, its salts and esters	All products	0.5 per cent (expressed as acid)	A	—	—
2	Propionic acid and its salts	All products	2 per cent (expressed as acid)	A	—	—
3	Salicylic acid and its salts	All products	0.5 per cent (expressed as acid)	A	Not to be used in preparations for children under three years of age except for shampoos	Not to be used for children under three years of age (solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	All products	0.6 per cent (expressed as acid)	A	—	—
5	Formaldehyde and para-formaldehyde	For oral hygiene Except for oral hygiene (see also	0.1 per cent (expressed as free formaldehyde) 0.2 per cent (expressed as free formaldehyde)	Not to be used in aerosol dispensers (sprays)	—	

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		Part I of Schedule 4)				
6	ENTRY DELETED					
7	Biphenyl-2-ol [o-phenylphenol] and its salts	All products	0.2 per cent (expressed as the phenol)	A	—	
8	Pyrithione zinc (INN) [Zinc pyrithione]	Products rinsed off after use	0.5 per cent	A	Not to be used in oral hygiene products	
9	Inorganic sulphites and hydrogen sulphites	All products	0.2 per cent (expressed as free SO ₂)	A	—	
10	Sodium iodate	Products rinsed off after use	0.1 per cent		—	
11	Chlorobutanol (INN)	All products	0.5 per cent	Not to be used in aerosol dispensers (sprays)	Contains chlorobutanol	
12	4-Hydroxybenzoic acid and its salts and esters [the Parabens]	All products	0.4 per cent (expressed as acid) for 1 ester, 0.8 per cent (expressed as acid) for mixtures of esters	A	—	
13	3-Acetyl-6-methylpyran-2,4(3H)-dione [Dehydroacetic acid] and its salts	All products	0.6 per cent (expressed as acid)	Not to be used in aerosol dispensers (sprays)	—	
14	Formic acid and its sodium salt	All products	0.5 per cent (expressed as acid)	A	—	
15	3,3'-Dibromo-4,4'-	All products	0.1 per cent		—	

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	hexamethylenedioxydi-benzamidine [Dibromo-hexamidine] and its salts (including isethionate)				
16	Thiomersal (INN) [Thimerosal]	Eye make-up and eye make-up remover	0.007 per cent calculated as mercury. When mixed with other authorised mercury compounds total mercury concentration must not exceed 0.007 per cent	—	Contains thiomersal
17	Phenylmercuric salts (including borate)	Eye make-up and eye make-up remover	0.007 per cent calculated as mercury. When mixed with other authorised mercury compounds total mercury concentration must not exceed 0.007 per cent	—	Contains phenylmercuric compounds
18	Undec-10-enoic acid [Undecylenic	All products	0.2 per cent (expressed as acid)	A	—

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	acid] and its salts				
19	Hexetidine (INN)	Products rinsed off after use	0.1 per cent	A	—
20	5-Bromo-5-nitro-1,3-dioxane	Products rinsed off after use	0.1 per cent	Avoid formation of nitrosamines	—
21	ENTRY DELETED				
22	2,4-Dichlorobenzyl alcohol [Dichlorobenzyl alcohol]	All products	0.15 per cent	A	—
23	Triclocarban (INN)	All products	0.2 per cent	A	Purity criteria: 3,3',4,4'-tetrachloroazobenzene < 1 mg/kg
24	4-Chloro- <i>m</i> -cresol [<i>p</i> -Chloro- <i>m</i> -cresol]	Not to be used in products intended to come into contact with mucous membranes	0.2 per cent	A	—
25	Triclosan (INN)	All products	0.3 per cent	A	—
26	4-Chloro-3,5-xylenol [Chloroxylenol]	All products	0.5 per cent	A	—
27	3,3'-Bis(1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methylenediurea [Imidazolidinyl urea]	All products	0.6 per cent	A	—

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28	Poly(1-hexamethylene-biguanide hydrochloride) [Polyaminopropyl biguanide]	All products	0.3 per cent	A	—	—
29	ENTRY DELETED					
30	Hexamethylenetetramine (Methenamine (INN)) [Methenamine]	All products	0.15 per cent	A	—	—
31	Methenamine 3-chloroallylchloride (INN) [Quaternium-15]	All products	0.2 per cent		—	—
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (Climbazole (INN)) [Climbazole]	All products	0.5 per cent	A	—	—
33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione [DMDM Hydantoin]	All products	0.6 per cent	A	—	—
34	Benzyl alcohol (See also Part I of Schedule 4)	All products	1.0 per cent	A	—	—
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-	Products rinsed off after use	1.0 per cent 0.5 per cent	A A	— —	— —

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	pyridone and its monoethanolamine salt [Piroctone olamine]	Other products			
36	1,2-Dibromo-2,4-dicyanobutane [Methyldibromoglutaronitrile]	All products	0.1 per cent	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025 per cent	—
37	6,6-Dibromo-4,4-dichloro-2,2'-methylenediphenol [Bromochlorophen]	All products	0.1 per cent	A	—
38	4-Isopropyl- <i>m</i> -cresol [o-Cymen-5-ol]	All products	0.1 per cent	—	—
39	Mixture of 5-chloro-2-methylisothiazol-3(2 <i>H</i>)-one and 2-methylisothiazol-3(2 <i>H</i>)-one with magnesium chloride and magnesium nitrate [Methylchloro-isothiazolinone and Methylisothiazolinone]	All products	0.0015 per cent of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2 <i>H</i>)-one to 2-methylisothiazol-3(2 <i>H</i>)-one	—	—
40	2-Benzyl-4-chlorophenol [Chlorophene]	All products	0.2 per cent	—	—
41	2-Chloroacetamide [Chloroacetamide]	All products	0.3 per cent	—	Contains chloroacetamide
42	Chlorhexidine (INN)	All products	0.3 per cent	A	—

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	and its digluconate, diacetate and dihydrochloride				
43	1-Phenoxypropanol [Phenoxyisopropanol] (see also Part I of Schedule 4)	Products intended for use after use	1.0 per cent	—	—
44	Alkyl (C12-C22)-trimethylammonium bromide and chloride (Cetrimonium bromide (INN) and Cetrimonium chloride (INNM))	All products	0.1 per cent	A	—
45	4,4-Dimethyl-1,3-oxazolidine [Dimethyloxazolidine]	All products	0.1 per cent	The pH of the finished product must not be lower than 6	—
46	1-[1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea [Diazolidinyl urea]	All products	0.5 per cent	—	—
47	Hexamidine (INN) (4,4'-(Hexamethylenedioxy)-dibenzamidine) and its salts, including isethionate and <i>p</i> -hydroxybenzoate	All products	0.1 per cent	A	—

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48	Glutaraldehyde (pentane-1,5-dial) [Glutaral]	All products	0.1 per cent	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05 per cent)
49	5-Ethyl-3,7-dioxo-1-azabicyclo[3.3.0]octane [7-Ethylbicyclo-oxazolidine]	All products	0.3 per cent	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	—
50	Chlorphenesin (INN) [Chlorphenesin]	All products	0.3 per cent	—	—
51	Sodium <i>N</i> -hydroxymethyl-glycinate [Sodium hydroxymethylglycinate]	All products	0.5 per cent	—	—
52	Silver chloride deposited on titanium dioxide	Not to be used in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips	0.004 per cent. calculated as silver chloride	The ratio of titanium dioxide to silver chloride shall be 4:1 by mass	—
53	Benzethonium chloride (INN)	Products rinsed off after use	0.1 per cent	—	—

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	[Benzethonium chloride]					
54	Benzalkonium chloride, bromide and saccharinate	All products	0.1 per cent calculated as benzalkonium chloride	A	—	Avoid contact with eyes
55	Benzylhemifosphate	Products rinsed off after use	0.15 per cent		—	—
56	3-Iodoprop-2-ynyl butylcarbamate [Iodopropynyl butylcarbamate]	Not to be used in oral hygiene and tip products	0.05 per cent		—	Contains iodine (Only required where the 3-iodoprop-2-ynyl butylcarbamate concentration in products intended to remain on the skin exceeds 0.02 per cent)

PART II

PRESERVATIVES LISTED IN ANNEX VI, PART 2 OF THE DIRECTIVE AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE SUPPLIED BEFORE A CERTAIN DATE

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>	(7) <i>Permitted for supply until</i>

Note: There are no entries in this Part at the date that these Regulations are made.

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