1987 No. 1920

CONSUMER PROTECTION

The Cosmetic Products (Safety) (Amendment) Regulations 1987

Made - - - -	*10th November 1987*
Laid before Parliament	*23rd November 1987*
Coming into force (except as provided in regulation 1)	*21st December 1987*

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987(**a**), consulted such organisations as appear to him to be representative of interests substantially affected by these Regulations, such other persons as he considers appropriate and the Health and Safety Commission;

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

Now, therefore, the Secretary of State in exercise of powers conferred on him by section 11 of the said Act of 1987 and by section 2 of the said Act of 1972 and of all other powers enabling him in that behalf hereby makes the following Regulations:

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) Regulations 1987 and except as provided by paragraph (2) below, shall come into force on 21st December 1987.

(2) Regulation 2(y), regulation 2(bb) insofar as it relates only to entry Number 52 in Schedule 1 to these Regulations, regulation 2(cc), regulation 2(ee) and regulation 2(ff) shall come into force–

(a) in relation to the supply, offering to supply, agreeing to supply, exposing for supply or possessing for supply of cosmetic products by the manufacturer in or importer into the United Kingdom or, in the case of cosmetic products, manufactured in or imported into the United Kingdom on behalf of another person, by that other person, on 1st January 1988, except where the cosmetic products are supplied, agreed to be supplied, exposed for supply or possessed for supply by retail in which case they shall come into force on 1st January 1989; and

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

(**a**) 1987 c.43. (**b**) S.I. 1972/1811, 1975/1707. (**c**) 1972 c.68.

2. The Cosmetic Products (Safety) Regulations 1984(a) are hereby amended–

(a) in regulation 4(1), in the definition of "the Directive", by the omission of the word "and" between "Council Directive No. 83/574/EEC" and "Commission Directive No. 83/496/EEC" and by the addition of the words "Commission Directive No. 84/415/EEC(j), Commission Directive No. 85/391/EEC(k), Commission Directive No. 85/490/EEC(l), Commission Directive No. 86/179/EEC(m) and Commission Directive No. 86/199/EEC(n)" and by the insertion as footnotes at the foot of the relevant page of the following–

"(j) O.J. L228, 25.8.84, p.31

(k) O.J. L224, 22.8.85, p.40

(l) O.J. L295, 7.11.85, p.30

(m) O.J. L138, 24.5.86, p.40

(n) O.J. L149, 3.6.86, p.38";

(b) in regulation 5(2) by the insertion after the word "manufacturer" of the word "in";

(c) in regulation 6(3) by the substitution for the words "3, 4 and 5" of the words "3, 4, 5 and (in the case of Part II) 7".

(d) in regulation 6 by the substitution for paragraph (4) of the following paragraph–

"(4) A cosmetic product shall not contain–

(a) any colouring agent listed in columns 1 and 2 of Schedule 3 unless–

(i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that colouring agent are satisfied; or

(ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that colouring agent are satisfied and the cosmetic product in question is supplied on or before the date specified in column 5 of that Part;

(b) any colouring agent which is not listed in that Schedule and which is intended to come into contact with the mucous membrane;"

(e) in regulation 6 by the omission of paragraph (5);

(f) in regulation 6(6) by the substitution for sub-paragraph (a) of the following sub-paragraph–

"(a) any preservative listed in column 2 of Schedule 5 unless–

(i) the requirements in columns 3, 4 and 5 of Part I of that Schedule in relation to that preservative are satisfied; or

(ii) the requirements in columns 3, 4 and 5 of Part II of that Schedule in relation to that preservative are satisfied and the preservative in question is supplied on or before the date specified in column 7 of that Part;"

(g) in regulation 6(6) by the omission of the word "and" between sub-paragraphs (a) and (b) and by the addition of the following sub-paragraph–

"(c) any preservative listed in column 2 of Part II of Schedule 5 after the date specified in column 7 of that Schedule";

(h) in regulation 6(7) by the omission of the word "and" between sub-paragraphs (a) and (b);

(i) in regulation 9 by the substitution for paragraph (2) of the following paragraph–

"(2) Regulations 5, 6 and 8 above do not apply in any case in which the cosmetic product is supplied, offered for supply, agreed to be supplied, exposed or possessed for supply for the purposes of exporting that product to any country which is not a member State of the European Economic Community";

(j) in Schedule 1 by the substitution for the words in column 2 of entry Number 24 of the words–

"4-(or *p*-)Aminobenzoic acid esters except glycerol 1-(4-aminobenzoate) when provisionally permitted for use as a UV filter in accordance with the requirements specified at Item 4 of Part II of Schedule 6";

(a) S.I. 1984/1260, amended by S.I. 1985/2045.

(k) in Schedule 1 by the substitution in column 2 of entry Number 64 for the letter "B" of the symbol "*";

(l) in Schedule 1 by the substitution for the words in column 2 of entry Number 85 of the words "4-Benzyloxyphenol";

(m) in Schedule 1 by the insertion in column 4 of entry Number 148A of the figure "366";

(n) in Schedule 1 by the substitution in column 2 of entry Number 212 for the words "column 4 of Part II of Schedule 2" of the words "column 5 of Part II of Schedule 2";

(o) in Schedule 1 by the substitution in column 2 of entry Number 213 for the words "column 4 of Part II of Schedule 2" of the words "column 5 of Part II of Schedule 2";

(p) in Schedule 1 by the insertion after entry Number 285 of the following entry–

"285A – 4-ethoxyphenol 348 178";

(q) in Schedule 1 by the substitution in column 2 of entry Number 348 for the words "Hydroquinone monobenzyl ether" of the words "Hydroquinone monobenzyl, monoethyl and monomethyl ethers";

(r) in Schedule 1 by the insertion in column 3 of entry Number 348 after the figure "431" of the figures "285A, 411A";

(s) in Schedule 1 by the substitution in column 2 of entry Number 395 for the words "Part II of Schedule 5" of the words "Part I of Schedule 5";

(t) in Schedule 1 by the substitution in column 2 of entry Number 397 for the words "column 4 of Part II of Schedule 2" of the words "column 5 of Part II of Schedule 2";

(u) in Schedule 1 by the insertion after entry Number 411 of the following entry–

"411A 4-methoxyphenol 348 178";

(v) in Schedule 1 by the substitution in column 2 of entry Number 562 for the words "Selenium and its compounds" of the words "Selenium and its compounds except when permitted under the restrictions laid down against entry Number 50 in Part I of Schedule 2";

(w) in Schedule 1 by the substitution in column 2 of entry Number 603 for the words "column 4 of Part II of Schedule 2" of the words "column 5 of Part II of Schedule 2";

(x) in Schedule 1 entry number 645A by the insertion in column 4 of the figure "366";

(y) in Schedule 1 by the renumbering and appropriate relocation in numerical order of entry Number 675 (Aristolochic acid and its salts) as entry Number 56A and by the insertion after entry Number 674 of following–

"676 2, 3, 7, 8-Tetrachlorodibenzo-p-dioxin – 367

677 2, 6-Dimethyl-1, 3-dioxan-4-yl acetate (Dimethoxane) – 368

678 Pyrithione sodium (INNM) – 369";

(z) in Part I of Schedule 2 by the substitution in column 3 of entry Number 11 for the words "use other than as a preservative (see also Part II of Schedule 5)" of the words "all purposes and products";

(aa) in Part I of Schedule 2 by the substitution for entry Number 45 of the following–

"45	1, 3-Bis (hydroxymethyl) imidazolidiene-2-thione	(a)	Hair-care preparations	2 per cent	Not to be used in aerosol dispensers (sprays)	Contains 1, 3-Bis (hydroxymethyl) imidazolidine-2-thione
		(b)	Nail-care preparations	2 per cent	pH as applied value must be less than 4";	

(bb) in Part I of Schedule 2 by the insertion after entry Number 49 of the additional entries set out in Schedule 1 to these Regulations;

(cc) in Schedule 2 by the substitution for Part II of Schedule 2 of the Part set out in Schedule 2 to these Regulations;

(dd) in Part III of Schedule 2 by the substitution in column 3 of entry number 4 for the words "(See also Part II of Schedule 5)" of the words "(See also Part I of Schedule 5)";

(ee) by the substitution for Schedule 3 of the Schedule set out in Schedule 3 to these Regulations and by the omission of Schedule 4;

(ff) by the substitution for Schedule 5 of the schedule set out in Schedule 4 to these Regulations;

(gg) in Schedule 7 by the insertion in paragraph 1 after the words "Commission Directive No. 83/514/EEC;" of the words " "Annex D" means the Annex to Commission Directive No. 85/490/EEC*(a)*" and by the insertion as a footnote at the foot of the relevant page of "(a) O.J. No. L295, 7.11.85, p.30."

(hh) in Schedule 7 by the insertion after entry Number 6(26) of the following–

"(27) Any test for the identification and determination of the amount of glycerol 1-(4-aminobenzoate) in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of glycerol 1-(4-aminobenzoate)".

(28) Any test to determine the amount of chlorobutanol in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Determination of chlorobutanol".

(29) Any test for the identification and determination of the amount of quinine in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of quinine".

(30) Any test for the identification and determination of inorganic sulphites and hydrogen sulphites in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of inorganic sulphites and hydrogen sulphites".

(31) Any test for the identification and determination of chlorates of the alkali metals in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of chlorates of the alkali metals".

(32) Any test for the identification and determination of sodium iodate in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of sodium iodate".".

Francis Maude
Parliamentary Under-Secretary of State,
Department of Trade and Industry

10th November 1987

SCHEDULE 1

Regulation 2(bb)

Column 1 *Reference Number*	Column 2 *Name of substance*	Column 3 *Purpose of substance or type of product*	Column 4 *Maximum concentration of substance in product*	Column 5 *Other requirements*	Column 6 *Required information*
50	Selenium disulphide	Anti-dandruff shampoos	1 per cent		Contains selenium disulphide. Avoid contact with eyes or damaged skin
51	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_y CL_z$ and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	20 per cent as anhydrous aluminium zirconium chloride hydroxide 5.4 per cent as zirconium	The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 The ratio of the number of (Al + Zr) atoms to chlorine atoms must be between 0.9 and 2.1. Not to be used in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin
52	Quinolin–8–ol and bis (8–hydroxyquinolinium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations	0.3 per cent calculated as base		

SCHEDULE 2

Regulation 2(cc)

PART II

SUBSTANCES LISTED IN ANNEX IV, PART I OF THE DIRECTIVE AS SUBSTANCES PROVISIONALLY ALLOWED

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
Reference Number	*Name of substance*	*Purpose of substance or type of product*	*Maximum concentration of substance in product*	*Other requirements*	*Required information*	*Permitted for use until*
1	Methanol	Denaturant for ethanol and isopropyl alcohol	5 per cent calculated as a percentage of ethanol and isopropyl alcohol	—	—	31.12.1987
2	1,1,1–Trichloroethane (methyl chloroform)	Aerosol spray	35 per cent (When mixed with dichloromethane total concentration must not exceed 35 per cent)	—	Do not spray on a naked flame or any incandescent material	31.12.1987
3	3,4′,5–Tribromosalicylanilide (Tribromsalan)	Deodorant soaps	1 per cent	Purity of the 3,4′,5–Tribromosalicylanilide: must be not less than 98.5 per cent Other bromosalicylanilides: not to exceed 1.5 per cent 4′,5–dibromosalicylanilide: not to exceed 0.1 per cent Inorganic bromide: not to exceed 0.1 per cent expressed as NaBr	Contains tribromosalicylanilide	31.12.1987
4	2,2′–Dithiobis (pyridine 1–oxide), addition product with magnesium sulphate trihydrate	Rinsed off hair care products	1 per cent	—	—	31.12.1987
5	1–Phenoxypropan–2–ol	–Rinse-off products only –Prohibited in oral hygiene products	2 per cent	For preservative use see Schedule 5 – Part II – No 11	—	31.12.1987

SCHEDULE 3 Regulation 2(ee)

SCHEDULE 3 Regulation 6(4)

COLOURING AGENTS

In this Schedule the colouring agents referred to in regulation 6(4)(a) are–

(i) those identified either by name or by colour index number (the colour index numbers being those specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists);

(ii) lakes or salts of these colouring agents which do not use substances prohibited under Annex II or which are excluded under Annex V from the scope of the Cosmetics Directive (76/768/EEC).

In the case of colouring agents identified by the addition of (*) to the name or colour index number, 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 Article 8 of the Directive.

Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 23 October 1962 on the approximation of the rules of Member States concerning foodstuffs and colouring matters(**a**), as amended,(**b**) and adapted(**c**) must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter 'E' has been deleted therefrom.

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

(**b**) Council Directives Nos. 65/469/EEC, 67/653/EEC, 68/419/EEC, 70/758/EEC, 76/399/EEC and 78/144/EEC (O.J. Nos. L178, 26.10.1965, p. 2793; L263, 30.10.1967, p. 4; L309, 24.12.1968, p. 24; L157, 18.7.1970, p. 36; L108, 26.4.1976, p. 19; L44, 15.2.1978, p. 20).

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

PART I

COLOURING AGENTS LISTED IN ANNEX III PART 2 OF THE DIRECTIVE AS COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS

Field of application

In column 3 of this Schedule, the entry "x" in a sub-column means that the colouring agent must not be used other than as follows–

Sub-column 1 = Colouring agents allowed in all cosmetic products;

Sub-column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover;

Sub-column 3 = Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes;

Sub-column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
10006	Green				X	
10020	Green			X		
10316*	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
12075*	Orange	X				
12085*	Red	X				3 per cent maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	See also Part 2
13015	Yellow	X				E 105
13065	Yellow				X	See also Part 2
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E 125
15510*	Orange		X			
15525	Red	X				
15580	Red	X				

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
15585*	Red		X			
15620	Red				X	
15630*	Red	X				3 per cent maximum concentration in the finished product
15800	Red			X		See also Part 2
15850*	Red	X				
15865*	Red	X				
15880	Red	X				
15980	Orange	X				E 111
15985*	Yellow	X				E 110
16035	Red	X				
16185	Red	X				E 123
16230	Orange			X		
16255*	Red	X				E 124
16290	Red	X				E 126
17200	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140*	Yellow	X				E 102
20040	Yellow				X	Maximum 3, 3'–dimethylbenzidine concentration in the colouring agent : 5 ppm
20170	Orange			X		
20470	Black				X	See also Part 2
21100	Yellow				X	Maximum 3, 3'–dichloro-benzidine concentration in the colouring agent : 5 ppm
21108	Yellow				X	Maximum 3, 3'–dichloro-benzidine concentration in the colouring agent : 5 ppm
21230	Yellow			X		
24790	Red				X	
27290*	Red				X	
27755	Black	X				E 152
28440	Black	X				E 151
40215	Orange				X	

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
40800	Orange	X				
40820	Orange	X				E 160 e
40825	Orange	X				E 160 f
40850	Orange	X				E 161 g
42045	Blue				X	See also Part 2
42051*	Blue	X				E 131
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	See also Part 2
42510	Violet			X		
42520	Violet				X	5 ppm max concentration in the finished product
42640	Violet	X				
42735	Blue			X		
44045	Blue				X	See also Part 2
44090	Green	X				E 142
45100	Red				X	
45170*	Red	X				
45170:1			X			
45190	Violet				X	See also Part 2
45220	Red				X	
45350	Yellow	X				6 per cent max concentration in the finished product
45370*	Orange	X				Not more than 1 per cent 2–(6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid and 2 per cent 2–(bromo–6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid
45380*	Red	X				as immediately above
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 per cent
45405	Red		X			Not more than 1 per cent 2–(6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid and 2 per cent 2–(bromo–6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid
45410*	Red	X				as immediately above

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
45425	Red	X				Not more than 1 per cent 2–(6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid and 3 per cent 2–(iodo–6–hydroxy–3–oxo–3H–xanthen–9–yl) benzoic acid
45430*	Red	X				as immediately above E 127
47000	Yellow			X		See also Part 2
47005	Yellow	X				E 104
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				E 130
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				E 132
73360	Red	X				
73385	Violet	X				
73900	Violet				X	See also Part 2
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	See also Part 2
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				E 160 b
75125	Yellow	X				E 160 d
75130	Orange	X				E 160 a
75135	Yellow	X				E 161 d
75170	White	X				

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
77288	Green	X				Free from chromate ions
77289	Green	X				Free from chromate ions
77346	Green	X				
77400	Brown	X				
77480	Brown	X				E 175
77489	Orange	X				E 172
77491	Red	X				E 172
77492	Yellow	X				E 172
77499	Black	X				E 172
77510	Blue	X				Free from cyanide ions
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				E 174
77891	White	X				E 171
77947	White	X				
Lactoflavin	Yellow	X				E 101
Caramel	Brown	X				E 150
Capsanthin, capsorubin	Orange	X				E 160 c
Beetroot red	Red	X				E 162
Anthocyanins	Red	X				E 163
Aluminium, zinc, magnesium and calcium stearates	White	X				

Column 1	Column 2	Column 3				Column 4
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*
		1	*2*	*3*	*4*	
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	

PART II

COLOURING AGENTS LISTED IN ANNEX IV PART 2 OF THE DIRECTIVE AS COLOURING AGENTS PROVISONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS

Field of application

In column 3 of this Schedule the entry "X" in a sub-column means that the columns agent must not be used other than as follows–

Sub-column 1 = Colouring agents allowed in all cosmetic products;

Sub-column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover;

Sub-column 3 = Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes;

Sub-column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Column 1	Column 2	Column 3				Column 4	Column 5
Name or colour index number	*Colour*	*Type of product Field of application*				*Other requirements*	*Authorization valid until*
		1	*2*	*3*	*4*		
12700	Yellow			X		See also Part I	31.12.1987
13065	Yellow			X		See also Part I	31.12.1987
15800	Red	X				See also Part I	31.12.1988
19120	Yellow				X		31.12.1988
20470	Black			X		See also Part I	31.12.1988
21110	Orange				X	Maximum 3,3′–dichloro-benzidine concentration in the colouring agent: 5 ppm	31.12.1987
21115	Orange				X	as immediately above	31.12.1988
26100	Red	X					31.12.1988
42045	Blue			X		See also Part I	31.12.1988
42170	Green			X		See also Part I	31.12.1988
42535	Violet			X			31.12.1987
44025	Green				X		31.12.1987
44045	Blue			X		See also Part I	31.12.1987
45190	Violet			X		See also Part I	31.12.1988
47000	Yellow	X				See also Part I	31.12.1988
61554	Blue			X		Only in hair-care preparations in a maximum concentration of 50 ppm	31.12.1987
73312	Red				X		31.12.1987
73900	Violet			X		See also Part I	31.12.1987
73905	Red				X		31.12.1988
74180	Blue			X		See also Part I	31.12.1988
75660	Yellow				X		31.12.1988
Acid red 195	Red			X			31.12.1987

SCHEDULE 4 Regulation 2(ff)

SCHEDULE 5 Regulations 6(6) and 8(1)

PRESERVATIVES

In this Schedule, the matters specified in columns 3, 4, 5 and 6 which apply to a particular substance are those set out to the right of its name as mentioned in column 2; and the matters specified in columns 4, 5 and 6 which apply in any particular case are those set out to the right of the matter specified in column 3 which applies in that case. The substance may not be 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.

PART I

PRESERVATIVES LISTED IN ANNEX VI, PART I OF THE DIRECTIVE AS PRESERVATIVES ALLOWED

Column 1 *Reference Number*	Column 2 *Name of substance*	Column 3 *Purpose of substance or type of product*	Column 4 *Maximum concentration of substance in product*	Column 5 *Other requirements*	Column 6 *Required information*
1	Benzoic acid, its salts and esters	All products	0.5 per cent (acid) A	—	—
2	Propionic acid and its salts	All products	2 per cent (acid) A	—	—
3	Salicylic acid and its salts	All products	0.5 per cent (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 (acid) A	—	—
5	Formaldehyde and paraformaldehyde	Oral hygiene products Other products (see also Part I of Schedule 2)	0.1 per cent (expressed as free formaldehyde) 0.2 per cent (expressed as free formaldehyde)	Not to be used in aerosol dispensers (sprays)	—
6	Hexachlorophene (INN)	All products	0.1 per cent	–Not to be used in products for children less than three years old or in personal hygiene products. –Purity criterion: absence of 2,3,7,8–tetrachlorodibenzo–*p*–dioxin	Not to be used for children under three years of age. Contains hexachlorophene
7	Biphenyl–2–ol (o–phenylphenol) and its salts	All products	0.2 per cent expressed as the phenol A	—	—
8	Pyrithione zinc (INN)	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 A expressed as free SO_2	—	—

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Reference Number	*Name of substance*	*Purpose of substance or type of product*	*Maximum concentration of substance in product*	*Other requirements*	*Required information*
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	All products	0.4 per cent (acid) for 1 ester, 0.8 per cent (acid) for mixtures of esters A	—	—
13	3–Acetyl–6–methylpyran–2,4 (3H)–dione (Dehydracetic acid) and its salts	All products	0.6 per cent (acid)	Not to be used in aerosol dispensers (sprays)	—
14	Formic acid	All products	0.5 per cent (acid) A	—	—
15	3,3'–Dibromo–4,4' –hexamethylene –dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	All products	0.1 per cent	—	—
16	Thiomersal (INN)	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 and its salts	All products	0.2 per cent (acid) A	See also Schedule 5, Part II, Item 8	—
19	Hexetidine (INN)	Rinse-off products only	0.1 per cent A	See also Schedule 5, Part II, Item 15	—
20	5–Bromo–5–nitro–1, 3–dioxane	Rinse-off products only	0.1 per cent	Avoid formation of nitrosamines See Schedule 5, Part II, No. 7	—

Column 1	Column 2	Column 3	Column 4		Column 5	Column 6
Reference Number	*Name of substance*	*Purpose of substance or type of product*	*Maximum concentration of substance in product*		*Other requirements*	*Required information*
21	Bronopol (INN)	All products	0.1 per cent	A	Avoid formation of nitrosamines	—
22	2,4–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 ppm 3,3′,4,4′–Tetrachloroazoxybenzene 1 ppm	—
24	4–Chloro–m–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	All products	0.5 per cent	A	—	—
27	3,3′–Bis(1–hydroxymethyl –2,5–dioxoimidazolidin–4–yl) –1,1′–methylenediurea ("Imidazolidinyl urea")	All products	0.6 per cent	A	—	—
28	Poly(1–hexamethylenebiguanide hydrochloride)	All products	0.3 per cent	A	—	—
29	2–Phenoxyethanol	All products	1.0 per cent	A	—	—
30	Hexamethylenetetramine (methenamine (INN))	All products	0.15 per cent	A	—	—
31	Methenamine 3–chloroallylochloride (INNM)	All products	0.2 per cent		—	—
32	1–(4–Chlorophenoxy)–1 –(imidazol–1–yl)–3,3–di– methylbutan–2–one	All products	0.5 per cent	A	—	—
33	1,3–Bis(hydroxymethyl)–5,5– dimethylimidazolidine–2,4–dione	All products	0.6 per cent	A	—	—

Column 1	Column 2	Column 3	Column 4		Column 5	Column 6
Reference Number	*Name of substance*	*Purpose of substance or type of product*	*Maximum concentration of substance in product*		*Other requirements*	*Required information*
34	Benzyl alcohol	All products (See also Schedule 2 Part I, No. 46)	1.0 per cent	A	—	—
35	1–Hydroxy–4–methyl–6–(2,4,4–trimethylpentyl)–2–pyridone and its monoethanolamine salt	Rinse-off products only	1.0 per cent	A	—	—
		For other products	0.5 per cent	A		
36	1,2–Dibromo–2,4–dicyanobutane	All products	0.1 per cent		Not to be used in cosmetic sunscreen products	—
37	6,6–Dibromo–4,4–dichloro–2,2'–methylenediphenol (Bromochlorophen)	All products	0.1 per cent	A	—	—
38	4–Isopropyl–*m*–cresol	All products	0.1 per cent		—	—
39	Mixture of 5–Chloro–2–methylisothiazol–3(2*H*)–one and 2–methylisothiazol–3(2*H*)–one with magnesium chloride and magnesium nitrate	All products	0.003 per cent of a mixture in the ratio 3:1 of 5–chloro–2–methylisothiazol–3(2H)–one and 2–methylisothiazol–3(2*H*)–one		—	—

PART II

PRESERVATIVES LISTED IN ANNEX VI PART 2 OF THE DIRECTIVE AS PRESERVATIVES PROVISIONALLY ALLOWED

Column 1	Column 2	Column 3	Column 4		Column 5	Column 6	Column 7
a	*b*		*c*		*d*	*e*	*f*
Reference Number	*Name of substance*	*Type of product*	*Maximum concentration of substance in product*		*Other limitations and requirements*	*Required information Conditions of use and warnings which must be printed on the label*	*Allowed until*
1	Boric acid	(a) Products for oral hygiene	0.5 per cent	A	—	—	31.12.1988
		(b) Other products (see also Schedule 2 Part 1, No. 1)	3.0 per cent	A			
2	Chlorphenesin (INN)	All products	0.5 per cent	A	—	—	31.12.1987
3	Dibromopropamidine (INN) and its salts (including isethionate (INN))	All products	0.1 per cent		—	—	31.12.1988
4	Alkyl (C12–C22) trimethyl–ammonium bromide and chloride (including Cetrimonium bromide (INN))	All products	0.1 per cent	A	—	—	31.12.1988
5	3–Heptyl–2–(3–heptyl–4 methyl–4–thiazolin–2–ylidenemethyl)–4–methyl–thiazolinium iodide	Creams, toilet lotions and shampoos	0.002 per cent		—	—	31.12.1988
6	4,4–Dimethyl–1,3–oxazolidine	Products rinsed off after use	0.1 per cent		The pH of the finished product shall not be lower than 6	—	31.12.1989
7	5–Bromo–5–nitro–1,3–dioxane	Non rinse-off products	0.1 per cent		Avoid formation of nitrosamines (See Schedule 5–Part I, No. 20)	—	31.12.1987

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
a	*b*		*c*	*d*	*e*	*f*
Reference Number	*Name of substance*	*Type of product*	*Maximum concentration of substance in product*	*Other limitations and requirements*	*Required information Conditions of use and warnings which must be printed on the label*	*Allowed until*
8	Undec–10–enoic acid: esters, the amide, the mono–and bis(2–hydroxethyl) amides and their sulphosuccinates	All products (See Schedule 5–Part I, No. 18)	0.2 per cent (acid) A	—	—	31.12.1987
9	Clorofene (INN)	All products	0.2 per cent	—	—	31.12.1987
10	2–Chloro–*N*–(hydroxymethyl) acetamide	Products rinsed off after use	0.3 per cent expressed as the chloracetamide	—	—	31.12.1987
11	1–Phenoxypropan–2–ol	Products rinsed off after use	1.0 per cent	For other uses see Schedule 2–Part II–No. 5	—	31.12.1987
12	Benzethonium chloride (INN)	Not to be used in products intended to come into contact with mucous membranes	0.1 per cent A	—	—	31.12.1988
13	Benzalkonium chloride (INN) bromide and saccharinate	All products	0.25 per cent A	—	—	31.12.1987
14	1–[1,3–Bis(hydroxymethyl)–2,5– dioxoimidazolidin–4– yl] 1,3–bis(hydroxymethyl) urea	All products	0.5 per cent	—	—	31.12.1987
15	Hexetidine (INN)	All products (See also Schedule 5, Part I, No. 19)	0.1 per cent	—	—	31.12.1987
16	4–Hydroxybenzoic acid benzyl ester	All products	0.1 per cent (acid)	—	—	31.12.1988
17	Hexamidine (INN) and its salts (including isethionate and 4–hydroxybenzoate)	All products	0.1 per cent A	—	—	31.12.1988

Column 1	Column 2	Column 3	Column 4		Column 5	Column 6	Column 7
a	*b*		*c*		*d*	*e*	*f*
Reference Number	*Name of substance*	*Type of product*	*Maximum concentration of substance in product*		*Other limitations and requirements*	*Required information Conditions of use and warnings which must be printed on the label*	*Allowed until*
18	Benzylformal (a 1:1 mixture of benzyloxymethanol and (benzyloxymethoxy) methanol)	All products	0.2 per cent		—	—	31.12.1987
19	2–Chloroacetamide	All products	0.3 per cent		—	Contains chloroacetamide	31.12.1987
20	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	All products	0.3 per cent	A	—	—	31.12.1987
21	1,3,5–Tris(2–hydroxyethyl) hexahydro–1,3,5–triazine	Products rinsed off after use	0.2 per cent		—	Contains 1,3,5–Tris(2–hydroxyethyl) hexahydro–1,3,5 triazine	31.12.1988

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 1984 ("the Principal Regulations") as amended by the Cosmetic Products (Safety) (Amendment) Regulations 1985, and implement Commission Directives No. 85/391/EEC (O.J. L224, 22.8.85, p. 40), No. 85/490/EEC (O.J. L295, 7.11.85, p. 30), No. 86/179/EEC (O.J. L138, 24.5.86 p. 40) and No. 86/199/EEC (O.J. L149, 3.6.86 p. 38) on cosmetic products, and as permitted by the Directives impose certain additional requirements on the composition of cosmetic products. The Regulations are made under the Consumer Protection Act 1987 and the European Communities Act 1972.

The main changes are–

(1) the deletion of Schedules 3 and 4 of the principal Regulations and their replacement by the Schedule set out in Schedule 3 to these Regulations. The replacement Schedule lists colouring agents which are acceptable throughout the European Community and take account of the review of provisionally approved colourants undertaken to satisfy Article 5 of the Cosmetics Directive (76/768/EEC) (regulation 2(ee));

(2) the replacement of Schedule 5 of the principal Regulations by the Schedule set out in Schedule 4 to the Regulations. The Schedule lists the preservatives which may be used in cosmetic products and takes account of the review of provisionally approved preservatives undertaken to satisfy Article 5 of the Cosmetics Directive (76/768/EEC) (regulation 2(ff));

(3) the amendment of the wording of regulations 5(2) and 9(2) to make it clear that the controls over supply also apply to products exported to other member States of the European Economic Community (regulation 2(b) and (i));

(4) the prohibition of the use of 2,3,7,8–tetrachlorodibenzo–p–dioxin, dimethoxane, pyrithione sodium and heightened versions of hydroquinone (regulation 2 (q) and (y));

(5) the restriction of the use of selenium disulphide, aluminium zirconium hydroxides, quinolin–8–ol and bis (8–hydroxyquinolinium) sulphate, 2, 2′ diothiobis (pyridine 1–oxide), addition product with magnesium sulphate trihydrate and 1–phenoxy-propan–2–ol and the modification of the restriction on the use of 1,3–Bis (Hydroxy-methyl) imidazolidene–2–thione (regulation 2(aa) (bb) and (cc));

(6) the specification of methods in certain cases for identifying and in all cases for determining the presence in cosmetic products of glycerol 1–(4 aminobenzoate);, chlorobutanol, quinine, inorganic sulphites and hydrogen sulphites, chlorates of the alkali metal and sodium iodate (regulation 2(hh)).