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STATUTORY INSTRUMENTS

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**1993 No. 1539**

**CONSUMER PROTECTION**

**The Cosmetic Products (Safety) (Amendment) Regulations 1993**

<i>Made</i>	- - - -	<i>18th June 1993</i>
<i>Laid before Parliament</i>		<i>21st June 1993</i>
<i>Coming into force</i> <i>(except as provided in</i> <i>regulation 1(2))</i>		<i>21st June 1993</i>

Whereas the Secretary of State is a Minister designated<sup>(1)</sup> for the purposes of section 2 of the European Communities Act 1972<sup>(2)</sup> 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 2 of the said Act of 1972 hereby makes the following Regulations:—

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) Regulations 1993 and except as provided by paragraph (2) below shall come into force on 21st June 1993.

(2) Regulation 2(b) and regulation 2(c) shall come into force—

- (a) on 1st July 1993 in relation to the supply of cosmetic products by the manufacturer in or importer into the United Kingdom, or in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person, except where the cosmetic products are supplied by retail in which case they shall come into force on 1st July 1994; and
- (b) in all other cases on 1st July 1994.

2. The Cosmetic Products (Safety) Regulations 1989<sup>(3)</sup> are hereby amended—

- (a) in regulation 2(1) in the definition of “the Directive” by the substitution for “and” of “,” between the words “Commission Directives Nos.91/184/EEC(j)” and “92/8/EEC(k)” and by the addition of the words “and Commission Directive 92/86/EEC(l)” at the end of the definition and by the insertion of a footnote at the foot of the relevant page the following

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(1) S.I. 1972/1811, 1975/1707.

(2) 1972 c. 68.

(3) S.I. 1989/2233, amended by S.I. 1990/1812, S.I. 1991/447, S.I. 1992/1525.

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“(1) O.J. L325 11.11.92, p. 18.”;

(b) in Schedule 1—

(i) by the insertion after entry number 103 of the following—

“103A	Bis(hydroxyalkyl)amides not further N- substituted	—	411”;
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(ii) by the insertion after entry number 188A of the following—

“188B	Colouring agent CI — 15585	—	401”;
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(iii) in entry number 190C by the substitution for “CI 4517:1” of “CI 45170:1”;

(iv) by the insertion after entry number 221 of the following—

“221A	2-(2,4- Diaminophenyl)ethanol and its salts	—	407”;
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(v) by the insertion after entry number 294 of the following—

“294A	1,2-Epoxybutane	—	400”;
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(vi) by the insertion after entry number 301 of the following—

“301A	4-Ethoxy- <i>m</i> - phenylenediamine and its salts	—	406”;
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(vii) by the insertion after entry number 480 of the following—

“480A	Nitrosamines	—	410”;
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(viii) by the insertion after entry number 564 of the following—

“564A	Pramocaine (INN)	564B	405
564B	Pramoxine	564A	405”;

(ix) by the insertion after entry number 582 of the following—

“582A	Pyrocatechol	—	408
582B	Pyrogallol	—	409”;

(x) by the insertion after entry number 591 of the following—

“591A	Secondary dialkanolamines	103A	411”;
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(xi) by the insertion after entry number 601 of the following—

“601A	Strontium lactate	—	402
601B	Strontium nitrate	—	403
601C	Strontium polycarboxylate	—	404”;

(c) in Schedule 2, Part I—

(i) in column 6 of entry numbers 8, 9 and 10 by the deletion of — “Sensitivity test advisable before use”;

(ii) by the substitution for entry number 12 of the following—

“12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide including hydrogen peroxide-urea (hydrogen peroxide-carbamide) and zinc peroxide	(a) Hair- 12 per cent care of H <sub>2</sub> O <sub>2</sub> preparations or released	—	(a) (b) (c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them
		(b) Skin- 4 per cent care of H <sub>2</sub> O <sub>2</sub> preparations or released	—	
		(c) Nail hardener H <sub>2</sub> O <sub>2</sub> preparations or released	—	
		(d) Oral hygiene products	0.1 per cent H <sub>2</sub> O <sub>2</sub> present or released	

(iii) by the deletion of entry number 20; and

(iv) by the insertion after entry number 56 of the following—

“57	Strontium chloride hexahydrate	Toothpaste	3.5 per cent calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not	—	Contains strontium chloride. Use by children is not advisable
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			exceed 3.5 per cent		
58	Strontium acetate hemihydrate	Toothpaste	3.5 per cent calculated as strontium when mixed with other permitted strontium compounds the total strontium content must not exceed 3.5 per cent	—	Contains strontium acetate. Use by children is not advisable
59	Talc: Hydrated magnesium silicate	Talcum powders intended to be used for children under 3 years of age		—	Keep powder away from baby's nose and mouth
60	Fatty acid dialkanolamines	All purposes and products	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum N-nitrosodialkanolamine content: 50 µg/kg. (applies to raw materials) Keep in nitrite-free containers	—
61	Monoalkanolamines	All purposes and products	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Minimum	—

									<p>purity: 99 per cent. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum N-nitrosodialkanolamine content: 50 µg/kg. (applies to raw materials). Keep in nitrite-free containers</p>
62	Trialkanolamines	(a) non-rinse off products (b) other —” products	(a) 2.5	(a) (b): Do not use with nitrosating systems.	—				<p>Minimum purity 99 per cent. Maximum dialkanolamine content 0.5 per cent (applies to raw materials). Maximum N-nitrosodialkanolamine content: 50 µg/kg. (applies to raw materials). Keep in nitrite-free containers</p>

(d) in Schedule 2 Part II by the deletion of entry number 2;

(e) in Schedule 3 Part I—

(i) by the insertion following colour index number 24790 of the following—

“26100	Red	—	—	x	—	Purity criteria:
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aniline  
≤0.2 per  
cent

2-  
naphthol  
≤0.2 per  
cent

azobenzene-4-  
amine  
≤0.1 per  
cent

1-  
phenylazo-2-  
naphthol  
≤3 per  
cent

1-[2-  
(phenylazo)phenylazo]-2-naphthol  
≤2 per  
cent”;

- (ii) in the entries relating to colour index numbers 73900 and 74180 by the deletion of “See also Part II”;
- (f) in Schedule 3 Part II by the deletion of Solvent Yellow 98, colour index numbers 15585, 26100, 73900 and 74180 and the entries relating thereto;
- (g) in Schedule 4 Part I—
- (i) in column 5 of entry number 36 by the substitution for “not to be used in cosmetic sunscreen products” of “not to be used in cosmetic sunscreen products at a concentration exceeding 0.025 per cent”;
- (ii) in entry number 44 by the substitution for “Alkyl(C12-C22)trimethylammonium bromide and chlorine” of “Alkyl(C12-C22)trimethylammonium bromide and chloride (Cetrimonium bromide (INN) and Cetrimonium chloride (INN))”;
- (iii) in entry number 46 by the substitution for “1-[1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3bis(hydroxymethyl)urea” of “1-[1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3bis(hydroxymethyl)urea”; and
- (iv) by the insertion after entry number 46 of the following—

“47	HexamidineAll (INN) products (4,4- (Hexamethylenedioxy)- dibenzamidine) and its	0.1 per cent	A	—	—”;
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salts,  
including  
isethionate  
and *p*-  
hydroxybenzoate

(h) in Schedule 4 Part II

- (i) in entry numbers 2, 21, 26 and 27 by the substitution for “30.6.1992” of “30.6.1993”;  
(ii) in entry number 28 by the substitution for “31.12.1992” of “30.6.1993”;  
(iii) by the deletion of entry number 20;  
(iv) by the deletion of entry numbers 15 and 16 and the entries relating thereto and the substitution for them of the following—

“15	Benzethonium chloride (INN) (Benzyl- dimethyl- (2-{2- [4-]1,1,3,3- tetramethylbutyl- phenoxy}ethoxy- chloride)	Deodorants, hair-care products aftershave products	0.1 per cent	Not permitted in products intended to come into contact with mucous membranes	—	30.6.1993
16	Benzalkonium chloride (INN), bromide and saccharinate (Alkyl(C8- C18)benzyl- dimethylammonium chloride, bromide and saccharinate)	All products	0.1 per cent	A	—	30.6.1993”;

(v) by the insertion after entry 28 of the following:

“29	3- Iodoprop-2- ynylbutylcarbamate	All products	0.1 per cent	—	—	30.6.1993
30	Sodium N- hydroxymethylglycinate	All products	0.1 per cent	A	—	30.6.1993”;

(i) in Schedule 5 Part II—

- (i) the deletion of entry numbers 1, 4 and 16; and  
(ii) in entry numbers 2, 5, 6, 12, 13, 17, 24, 25, 26, 28, 29, 31 and 32 by the substitution for “30.6.1992” of “30.6.1993”.

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18th June 1993

*Denton of Wakefield*  
Parliamentary Under Secretary of State  
Department of Trade and Industry



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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Cosmetic Products (Safety) Regulations 1989 (S.I.1989/2233) (“the Principal Regulations”) as amended by the Cosmetic Products (Safety) (Amendment) Regulations 1990 (S.I.1990/1812), the Cosmetic Products (Safety) (Amendment) Regulations 1991 (S.I.1991/447) and the Cosmetic Products (Safety) (Amendment) Regulations 1992 (S.I.1992/1525).

They implement Commission Directive 92/86/EEC (O.J.No L325, 11.11.92, p. 18) by amending the Principal Regulations to—

(1) Prohibit 12 substances from use in cosmetic products, the substances being Bis(hydroxyalkyl)amines, not further N-substituted (secondary dialkanolamines); colouring agent CI 15585; 2-(2,4-Diaminophenyl)ethanol and its salts; 1,2-Epoxybutane; 4-Ethoxy-*m*-phenylenediamine and its salts; Nitrosamines; Pramocaine (INN); Pramoxine; Pyrocatechol; Pyrogallol; Strontium lactate; Strontium nitrate; and Strontium polycarboxylate (regulation 2(b)).

(2) Delete certain of the warning labelling requirements in respect of certain Phenylenediamines, Methylphenylenediamines and their N-substituted derivatives and salts, and Diaminophenols (regulation 2(c)(i)).

(3) Permit, subject to restrictions, the use of Hydrogen peroxide in oral hygiene products (regulation 2(c)(iii)).

(4) Permit, subject to restrictions, the use of Strontium chloride hexahydrate and Strontium acetate hemihydrate in toothpaste, impose labelling requirements in respect of talcum powders intended to be used for children under 3 years of age, and permit, subject to restrictions, the use of Fatty acid dialkanolamides, Monoalkanolamines and Trialkanolamines in cosmetic products (regulation 2(c)(iv)).

(5) Delete the provisional use of 1,1,1-Trichloroethane (regulation 2(d)).

(6) Permit, subject to restrictions, the use of colouring agent CI 26100 (regulation 2(e)).

(7) Delete from the list of provisionally approved colouring agents Solvent Yellow 98, CI 73900 and CI 74180 (regulation 2(f)).

(8) Permit as a preservative in cosmetic sunscreen products the use of 1,2-Dibromo-2,4-dicyanobutane at a maximum concentration of 0.025 per cent, and permit on a permanently approved basis the use subject to limitation as a preservative of Hexamidine (INN). Extend the allowed use of 7 provisionally allowed preservatives until 30th June 1993 and permit provisionally subject to restrictions the use of 2 others (regulation 2(g) and (h)).

(9) Delete three provisionally permitted UV filters, N-propoxylated ethyl 4-bisaminobenzoate, mixed isomers; Glycerol 1-(4-aminobenzoate); and Mexenone (INN) (regulation 2(i)(i)).

(10) Extend subject to restrictions the permitted use of 13 UV filters in cosmetic products until 30th June 1993 (regulation 2(i)(ii)).

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colorists, PO Box No 224, 82, Grafton Road, Bradford, BD1 2JB.