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STATUTORY INSTRUMENTS

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**1991 No. 447**

**CONSUMER PROTECTION**

**The Cosmetic Products (Safety) (Amendment) Regulations 1991**

<i>Made</i>	- - - -	<i>4th March 1991</i>
<i>Laid before Parliament</i>		<i>8th March 1991</i>
<i>Coming into force</i> <i>(except as provided in</i> <i>regulation 1(2) and (3))</i>		<i>31st March 1991</i>

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987<sup>(1)</sup>, 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<sup>(2)</sup> for the purposes of section 2 of the European Communities Act 1972<sup>(3)</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 sections 11, 28 and 30 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 1991 and except as provided by paragraphs 2 and 3 below shall come into force on 31st March 1991.

(2) Regulation 2(b) shall come into force—

- (a) on 31 March 1991 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 it shall come into force on 1 January 1992; and
- (b) in all other cases on 1 January 1992.

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(1) 1987 c. 43.

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

(3) 1972 c. 68.

- (3) Regulation 2(c), regulation 2(f), regulation 2(g) and regulation 2(h) shall come into force—
- (a) on 1 January 1992 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 1 January 1994; and
- (b) in all other cases on 1 January 1994.

2. The Cosmetic Products (Safety) Regulations 1989(4) are hereby amended—

- (a) in regulation 2(1) in the definition of “the Directive” by the deletion of the word “and” between “Council Directive No.88/667/EEC” and “Commission Directive No. 89/174/EEC” and by the addition of the words “, Council Directive No. 89/679/EEC(h) and Commission Directive No. 90/121/EEC(i)” and by the insertion as footnotes at the foot of the relevant page the following—

“(h) O.J. L398 30.12.89, p.25.

(i) O.J. L71, 17.3.90, p.40.”;

- (b) in Schedule 1—

- (i) by the insertion after entry number 1 of the following—

“1A	Acetonitrile	—	393”;
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- (ii) by the insertion after entry number 54 of the following—

“54A	Anti-androgens with steroid structure	—	390”;
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- (iii) in entry number 55 by the deletion of

“(except tyrothricin)”;

- (iv) by the insertion after entry number 188 of the following—

“188A	Colouring agent CI 13065	—	387”;
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- (v) by the insertion after entry number 189 of the following—

“189A	Colouring agent CI 42535	—	388”;
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- (vi) by the insertion after entry number 190 of the following—

“190A	Colouring agent CI 42640	—	386;
190B	Colouring agent CI 61554	—	389”;

- (vii) by the insertion after entry number 374 of the following—

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(4) S.I. 1989/2233, amended by S.I. 1990/1812.

“374A	11 $\alpha$ .- Hydroxypregn-4- ene-3, 20-dione and its esters	—	385”;
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(viii) in entry number 399 by the substitution for  
“(except lead acetate)” of “(except lead acetate subject to the restrictions laid down  
in entry number 55 in Part I of Schedule II)”;

(ix) in entry number 428 by the insertion of  
“and its salts”;

(x) in entry number 429 by the insertion of  
“and its salts”;

(xi) in entry number 568 by the deletion of  
“(except progesterone and ethisterone)”;

(xii) by the insertion after entry number 643 of the following—

“643A	Tetrahydrozoline and its salts	—	394”;
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(xiii) by the insertion after entry number 695 of the following—

“695A	Tyrothricin	—	392”;
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(xiv) by the insertion after entry number 709 of the following—

“709A	Zirconium and its compounds (except for aluminium zirconium chloride hydroxide complexes $A1_xZr(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes under the conditions laid down in Part I of Schedule 2 and zirconium lakes, salts and pigments prepared from those colouring agents identified in column 1 of Part I of the Schedule 3 by “*” immediately after the name or colour index number)	—	391”;
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(c) in Schedule 2, Part I by the insertion after entry number 54 of the following—

“55	Lead acetate	Only for hair dyeing	0.6% calculated as lead	—	Keep away from children. Avoid all contact with the eyes. Wash hands after use. Contains lead acetate. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops, discontinue use”;
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(d) in Schedule 2 Part II in entry numbers 2 and 4 by the substitution for “31.12.1989” of “31.12.1990”;

(e) in Schedule 2 Part III by the deletion of entry number 1;

(f) in Schedule 3 Part I—

- (i) by the deletion of colour index number 42640 and the entries relating thereto;
- (ii) by the deletion of the cross sign “x” from sub-column 4 of column 3 relating respectively to colour index numbers 42045 and 44045 and by the insertion of the cross sign “x” in sub-column 3 of that column;
- (iii) by the deletion of “see also Part II” from column 4 relating respectively to colour index numbers 42045 and 44045;
- (iv) by the insertion of “\*” immediately after the colour index number in column 1 relating to colour index number 17200;

(g) in Schedule 3, Part II—

- (i) by the insertion at the end of the following colouring agent and the entries relating thereto—

“Solvent Yellow 98	Yellow	—	—	x	—	Only in nail care preparations maximum 0.5% in the final product	31.12.91”;
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(ii) by the deletion of colour index numbers 13065, 21110, 42535, 44045, 61554 and the entries relating thereto;

(iii) by the substitution for “31.12.1989” of “31.12.1990” in column 5 relating respectively to colour index numbers 26100 and 73900;

- (iv) by the substitution for “31.12.1990” of “31.12.1991” in column 5 relating to colour index number 74180;
- (h) in Schedule 4 Part II—
- (i) by the insertion after entry number 26 of the following—

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“27	3—	All	0.5%	—	—	31.12.1990”;
	Decyloxy—	products				
	2—					
	hydroxy—					
	1—					
	aminopropane					
	hydrochloride					
	(Decominol					
	(INN))					

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- (ii) in entry numbers 2, 4, 6, 15, 16, 17, 20 and 21 by the substitution for “31.12.1989” of “31.12.1990”; and

- (i) in Schedule 6 by the insertion in paragraph 1 after the words  
““Annex B” means the Annex to Commission Directive No. [82/434/EEC](#)” of  
the following—

“as amended by Commission Directive No. [90/207/EEC](#) (f)” and by the—  
insertion as a footnote at the foot of the relevant page of “(f) O.J. No. L108,  
28.4.90, p.92”.

4th March 1991

*Edward Leigh*  
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 as amended by the Cosmetic Products (Safety) (Amendment) Regulations 1990 (“the principal regulations”). They implement Commission Directive [90/12/EEC](#) by—

**1.** Prohibiting 12 substances from use in cosmetic products by the addition of their names to Schedule 1 to the principal regulations, the substances being acetonitrile, anti-androgens with steroid structure, colouring agents CI 13065, CI 42535, CI 42640 and CI 61554, 11 $\alpha$ -Hydroxypregn-4-ene-3,20-dione and its esters, the salts of 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole—CI 76050) and 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole), tetrahydrozoline and its salts, tyrothricin and zirconium (with the exception of two identified compounds) (regulation 2(b)).

**2.** Removing the authority to use tyrothricin, and progesterone and ethisterone by deleting the exemptions previously given for items 55 and 568 of Schedule 1 to the principal regulations (regulation 2(b)).

**3.** Restricting the use of lead acetate to use in hair-dyeing at a maximum concentration of 0.6% calculated as lead and subject to expanded labelling requirements (regulation 2(c)).

**4.** Extending until 31 December 1990, the provisionally approved use of 1,1,1-Trichloroethane (methyl chloroform) and 2,2-Dithiobis (pyridine 1-oxide) addition product with magnesium sulphate trihydrate (regulation 2(d)).

**5.** Amending restrictions on the use of colouring agents CI 42045 and CI 44045 and placing their use on a permanently approved basis (regulation 2(f)).

**6.** Permitting, subject to restrictions, the use of the insoluble barium, strontium and zirconium lakes, salts and pigments of colouring agent CI 17200 (regulation 2(f)).

**7.** Approving provisionally and until 31st December 1991, the use of Solvent Yellow 98 as a colouring agent in nail-care preparations (regulation 2(g)).

**8.** Placing on a permanently approved basis the use of colouring agent CI 21 100 (regulation 2(g)).

**9.** Extending the periods of authorisation for provisionally approved colouring agents CI 26100 and CI 73900 to 31 December 1990 and for colouring agent CI 74180 to 31 December 1991 (regulation 2(g)).

**10.** Permitting on a provisional basis and until 31 December 1990, the use of 3-Decylox-y-2-hydroxy-1-aminopropane hydrochloride as a preservative at a maximum concentration of 0.5% (regulation 2(h)).

**11.** Extending the allowed use of 8 provisionally allowed preservatives until 31 December 1990, those substances being, Chlorphenesin (INN), Alkyl (C12-C22) trimethylammonium bromide and chloride (including Cetrimonium bromide (INN)), 4,4-Dimethyl-1,3-oxazolidine, Benzethonium chloride (INN), Benzalkonium chloride (INN) bromide and saccharinate, 1-[1,3-Bis (hydroxymethyl)-2,5-dioximid-azolidin-4-yl]-1,3-bis (hydroxymethyl) urea, Hexamidine (INN) and its salts (including isethionate and 4-hydroxybenzoate) and Benzylhemiformal (a 1: 1 mixture of benzyloxymethanol and (benzyloxymethoxy) methanol) (regulation 2(h)).

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The Regulations also provide for certain changes to the procedures for determining the presence or concentration of free formaldehyde in a cosmetic product which are set out in Commission Directive [90/207/EEC](#) (regulation 2(i)).

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