
 STATUTORY INSTRUMENTS

1988 No. 2121

CONSUMER PROTECTION

 The Cosmetic Products (Safety) (Amendment No.2)
 Regulations 1988

<i>Made</i> - - - -	<i>6th December 1988</i>
<i>Laid before Parliament</i>	<i>9th December 1988</i>
<i>Coming into force (except as provided in regulation 1(2) and (3))</i>	<i>1st January 1989</i>

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 No.2) Regulations 1988 and, except as provided by paragraphs (2) and (3) below, shall come into force on 1st January 1989.

(2) Regulation 2(b) 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 1989, 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 1990: and

(b) in all other cases, on 1st January 1990.

(3) Regulation 2(c), (e), (g) and (h) 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 1990, except where the cosmetic products are supplied, agreed to

(a) 1987 c. 43.

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

(c) 1972 c. 68.

be supplied, exposed for supply or possessed for supply by retail in which case they shall come into force on 1st January 1992; and;

(b) in all other cases, on 1st January 1992.

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 “Commission Directive No. 87/137/EEC” and “Commission Directive No. 87/143/EEC” and by the addition of the words “and Commission Directive No. 88/233/EEC (q)” and by the insertion as a footnote at the foot of the relevant page of the following—

“(q) O.J. L105, 26.4.88, p. 11”;

(b) in Schedule 1 by—

(i) the deletion in entry Numbers 212, 213 and 397 of “(except as those impurities of tribromosalicylanide permitted in accordance with the requirements specified in column 5 of Part II of Schedule 2)”;

(ii) the insertion after entry Number 681 of the following—

“682 3,4',5-Tribromosalicylanilide (tribromosalan)	373
683 <i>Phytolacca</i> spp and their preparations	374
684 Tretinoin (retinoic acid and its salts)	375
685 1-Methoxy-2,4- diaminobenzene (2,4- diaminoanisole-CI 76050)	376
686 1-Methoxy-2,5- diaminobenzene (2,5- diaminoaninole)	377
687 Colouring agent CI 12140	378
688 Colouring agent CI 26105	379
689 Colouring agents CI 42555, CI 42555-1 and CI 42555-2”;	380

(c) in Part I of Schedule 2 by—

(i) the substitution for entry Numbers 2 and 52 of the following in their respective places—

"2a	Thioglycollic acid and its salts	<p>(a) Hair waving or straightening products:</p> <p>—general use</p> <p>—professional use</p> <p>(b) Depilatories</p> <p>(c) Other hair-care products which are removed after application</p>	<p>— 8 per cent ready for use</p> <p>—11 per cent ready for use</p> <p>— 5 per cent ready for use</p> <p>— 2 per cent ready for use</p>	<p>pH 7 to 9.5</p> <p>pH 7 to 9.5</p> <p>pH 7 to 12.7</p> <p>pH 7 to 9.5</p>	<p>The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences:</p> <p>—Avoid contact with eyes</p> <p>—In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice</p> <p>—Wear suitable gloves ((a) and (c) only)</p>	<p>(a):</p> <p>—Contains thioglycolate</p> <p>—Follow the instructions</p> <p>—Keep out of reach of children</p> <p>—For professional use only (where applicable)</p> <p>(b) and (c):</p> <p>—Contains thioglycolate</p> <p>—Follow the instructions</p> <p>—Keep out of reach of children</p>
2b	Thioglycollic acid esters	<p>Hair waving or straightening products:</p> <p>—general use</p> <p>—professional use</p>	<p>— 8 per cent ready for use</p> <p>—11 per cent ready for use</p> <p>The above-mentioned percentages are calculated as thioglycollic acid</p>	<p>pH 6 to 9.5</p> <p>pH 6 to 9.5</p>	<p>The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences:</p> <p>—May cause sensitization in the event of skin contact</p> <p>—Avoid contact with eyes</p> <p>—In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice</p> <p>—Wear suitable gloves</p>	<p>—Contains thioglycolate</p> <p>—Follow the instructions</p> <p>—Keep out of reach of children</p> <p>—For professional use only (where applicable)</p>
52	Quinolin-8-ol and bis (8-hydroxy-quinolium) sulphate	<p>Stabilizer for hydrogen peroxide in rinse-off hair-care preparations</p> <p>Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations</p>	<p>0.3 per cent calculated as base</p> <p>0.03 per cent calculated as base"</p>			

(ii) the insertion after entry Number 53 of the following—

“54	Etidronic acid and its salts (1-hydroxyethylidene-di-phosphonic acid and its salts)	(a) Hair-care (b) Soap	1.5 per cent 0.2 per cent	expressed as etidronic acid	—	Contains etidronic acid
55	1-Phenoxy-propan-2-ol	—Rinse-off products only —Prohibited in oral hygiene products	2 per cent		As a preservative, see Part 1 of Schedule 5”	—

(d) in Part II of Schedule 2 by the omission of entry Numbers 3 and 5 and the substitution in Column 7 relating to entry Numbers 2 and 4 of “31.12.89” for “31.12.1987”;

(e) in Part I of Schedule 3 by—

(i) the insertion at the end, in Column 1 of “Acid Red 195”, in Column 2 of “red” and in Column 3, sub-column 3, of “X”; and

(ii) the omission of the entries relating to colour index number 13065;

(f) in Part II of Schedule 3 by—

(i) the substitution in Column 5 relating to colour index numbers 13065, 21110, 42535, 44045, 61554 and 73900 of “31.12.1988” for “31.12.1987”;

(ii) the omission of the entries relating to name or colour index numbers 12700, 44025, 73312 and Acid red 195; and

(iii) the omission of the entry in Column 4 relating to colour index number 13065;

(g) in Part I of Schedule 5 by—

(i) the omission of the entry in Column 5 relating to entry number 19; and

(ii) the insertion

after entry Number 40 of the following—

“41	2-Chloroacetamide	All products	0.3 per cent	Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	All products	0.3 per cent A	— —
43	1-Phenoxypropan-2-ol	Rinse off products only”;	1 per cent	— —

(h) in Part II of Schedule 5 by—

(i) the omission of entry Numbers 7, 8, 9, 10, 11, 15, 19 and 20;

(ii) by the substitution in relation to entry Number 2 of “0.3 per cent A” for “0.5 per cent A” in Column 4 and of “31.12.1989” for “31.12.1987” in Column 7;

(iii) by the substitution in relation to entry Number 13 of “31.12.1988” for “31.12.1987” in Column 7;

(iv) by the substitution in relation to entry Number 14 of “31.12.1989” for “31.12.1987” in Column 7; and

(v) by the substitution in relation to entry Number 18 of the name “Benzylhemiformal” for “Benzylformal” in Column 2 and of “31.12.1989” for “31.12.1987”.

6th December 1988

Eric Forth
Parliamentary Under-Secretary of State,
Department of Trade and Industry

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 1984 ("the principal Regulations") and implement Commission Directive No. 88/233/EEC (O.J. No. L105, 26.4.88, p. 11) on cosmetic products.

The main changes are—

(1) The prohibition of five substances and five colouring agents from use in cosmetic products by the addition of their names to Schedule 1 to the principal Regulations. The substances in question are 3,4',5-tribromosalicylanilide (Tribromosalan), *Phytolacca Spp* and their preparations, Tretinoin or retinoic acid and its salts, 1-Methoxy-2,4-diaminobenzene, also known as 2,4-diaminoanisole, and 1-Methoxy-2,5-diaminobenzene, also known as 2,5-diaminoanisole. The five colouring agents are CI 12140, 26105, 42555, 42555-1 and 42555-2. The reference to substance 1-Methoxy-2,4-diaminobenzene has the Colour Index Number 76050 allocated to it.

(2) The clarification of the uses to which Thioglycollic acid is permitted to be put by distinguishing between the acid and its salts and the acid esters application and by further qualifying the purity criteria and amplifying the information and labelling requirements.

(3) The expansion of the existing controls over the use of Quinolin-8-ol and bis(8-hydroxyquinolinium) sulphate so as to permit use in non-rinse-off hair-care products but at a reduced concentration level.

(4) The introduction of controls relating to the use of Etidronic acid and its salts in cosmetic products.

(5) The placing on a permanent basis the previously provisional controls on the use of 1-Phenoxypropan-2-ol in cosmetic products.

(6) The amendment of the list of provisionally allowed substances at Schedule 2, Part II by extending the dates set for permission to use the substances 1,1,1-Trichloroethane (methyl chloroform) and 2,2'-Dithiobis (pyridene-1-oxide) and by deleting references to 3,4'5-Tribromosalicylanilide (Tribromosalan) and 1-Phenoxypropan-2-ol.

(7) The addition to the list of fully approved colouring agents at Schedule 3, Part I of the agent Acid Red 195 and the deletion of the reference to the colouring agent 13065.

(8) The amendment of the list of provisionally approved colouring agents at Schedule 3, Part II by extending the authorisation dates of agents 13065, 21110, 42535, 44045, 61554 and 73900, and removing from the list colouring agents 12700, 44025, 73312 and Acid Red 195.

(9) The addition to the list of fully allowed preservatives at Schedule 5, Part I of the substances 2-Chloroacetamide, Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride and 1-Phenoxypropan-2-ol at the conditions and levels previously allowed for provisionally approved use.

(10) The amendment of the list of provisionally allowed preservatives at Schedule 5, Part II by extending the authorisation dates for Chlorphenesin (INN), Benzalkonium chloride (INN), bromide and saccharinate; 1-(1,3-Bis(hydroxymethyl)2,5-dioximidazolidin-4-yl)-1,3-bis(hydroxymethyl) urea and Benzylhemiformal (until now shown as Benzylformal), amending the concentration level permitted for the use of Chlorphenesin and deleting references to 5-Bromo-5-nitro-1,3-dioxane, Undec-10-enoic acid and its associated forms, 2-Chloro-N-(hydroxymethyl) acetamide, 1-Phenoxypropan-2-ol, Hexidine (INN), 2-Chloroacetamide and Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride.

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colourists, PO Box No. 244, 82 Grattan Road, Bradford BD1 2JB.