
STATUTORY INSTRUMENTS

2004 No. 2988

CONSUMER PROTECTION

**The Cosmetic Products (Safety)
(Amendment) (No.2) Regulations 2004**

Made - - - - 15th November 2004
Laid before Parliament 16th November 2004
Coming into force - - 8th December 2004

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987⁽¹⁾, consulted such organisations as appear to her to be representative of interests substantially affected by the following Regulations, such other persons as she considers appropriate and the Health and Safety Commission;

Now, therefore, the Secretary of State in exercise of the powers conferred upon her by section 11 of the said Act hereby makes the following Regulations:

Citation, Commencement and Interpretation

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2004 and shall come into force on 8th December 2004.

(2) In these Regulations “the Principal Regulations” means the Cosmetic Products (Safety) Regulations 2004⁽²⁾.

Amendment to the Principal Regulations

2.—(1) The Principal Regulations are amended as follows.

(2) In regulation 5—

(a) for paragraph (15) there is substituted—

“(15) No cosmetic product containing any substance listed in Annex II to the Directive under entry numbers 452 to 1132 (inserted into the Directive by Directive [2004/93/EC](#)) shall be —

(a) placed on the market after 1st January 2005;

(b) supplied after 1st April 2005.”

(1) 1987 c. 43.

(2) S.I. [2004/2152](#) to which there are amendments not relevant to these Regulations.

- (b) in paragraph (16), “and (15)” is omitted.
- (3) In regulation 12(1), for “12” there is substituted “11”.
- (4) In regulation 13(2) for “under” there is substituted “of contravening a requirement of”.
- (5) In regulation 16—
 - (a) in paragraph (1)(a), for “5(11) and 5(12)” there is substituted “paragraphs 11 to 13 of regulation 5”;
 - (b) after paragraph (3) there is inserted the following—
 - “(3A) No proceedings shall be brought or enforcement action taken in respect of any contravention of a requirement of regulation 5(15) as it had effect before 8th December 2004.
 - (3B) No proceedings shall be brought or enforcement action taken in respect of any supply before 8th December 2004 of a cosmetic product containing any of the substances numbered 1 to 60 in Part 2 of Schedule 4 to these Regulations provided that—
 - (a) any requirements contained in columns 1 to 6 of Part 2 of Schedule 4 in relation to that substance were satisfied; and
 - (b) the cosmetic product satisfied the requirements of these Regulations, other than the requirements listed in Schedule 4.”
- (6) At the end of Schedule 2 there is inserted—
 - “**38.** Commission Directive 2004/87 (O.J. No. L287, 8.9.2004, p.4).
 - 39.** Commission Directive [2004/88/EC](#) (O.J. No. L287, 8.9.2004, p.5).
 - 40.** Commission Directive 2004/93 (O.J. No. L300, 25.9.2004, p.13).
 - 41.** Commission Directive [2004/94/EC](#) (O.J. No. L294, 17.9.2004, p.28).”
- (7) In Part 1 of Schedule 3, in entry 425 the following words are omitted—

“(except lead acetate subject to the restrictions laid down in entry number 55 in Part 1 of Schedule 4)”.
- (8) In Schedule 4—
 - (a) in Part 1—
 - (i) for entries 51, 53, 65 and 66 there are substituted the entries in the table in Part 1 of the Schedule to these Regulations;
 - (ii) for entry 55 there is substituted “ENTRY DELETED”;
 - (iii) in entry 60, in the fifth column, for “materials” where it first appears, there is substituted “materials”;
 - (iv) at the end, there are inserted the entries in Part 2 of the Schedule to these Regulations;
 - (b) in Part 2—
 - (i) in entries 1 to 60, for the date “30.9.2004” in the seventh column, wherever it occurs there is substituted “31.12.2005”;
 - (ii) entries 61 and 62 are omitted.
- (9) In Part 1 of Schedule 5 in entry 42051 there is inserted “E131” in the fourth column (Other requirement);
- (10) In Schedule 6—
 - (a) in the first paragraph, for “not calculated” there is substituted “be calculated”;
 - (b) in second paragraph—

- (i) for “In column 4” there is substituted “In column 5”;
- (ii) for “the limit set out in that column” there is substituted “the limit set out in column 4”;
- (c) in Part 1—
 - (i) for entry 5 there is substituted the entry in the table in Part 3 of the Schedule to these Regulations;
 - (ii) in entry 54, in the fourth column for “benzalkonoium” there is substituted “benzalkonium”.
- (11) In Part 1 of Schedule 7—
 - (a) in entry 11, for “Polyacrylamidomethyl” there is substituted “[Polyacrylamidomethyl”;
 - (b) in entry 19, for “[3-Benzylidene camphor” there is substituted “[3-Benzylidene camphor”].
- (12) Schedule 13 is omitted.

Gerry Sutcliffe
Parliamentary Under Secretary of State for
Employment Relations, Competition and
Consumers
Department of Trade and Industry

15th November 2004

Status: This is the original version (as it was originally made).

SCHEDULE

Regulation 2(8) and 2(10)

PART 1

ENTRIES TO BE SUBSTITUTED FOR ENTRIES 51, 53, 65 AND 66
IN PART 1 OF SCHEDULE 4 TO THE PRINCIPAL REGULATIONS

<i>(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
51	Quinolin-8- ol and bis(8- hydroxyquinolin- sulphate) (see also Part I of Schedule 3) [Oxyquinoline and Oxyquinoline sulphate]	Stabilizer for hydrogen peroxide in rinse-off hair care preparations	0.3 per cent calculated as base		
		Stabilizer for hydrogen peroxide in non rinse- off hair care preparations	0.03 per cent calculated as base		
53	Etidronic acid and its salts	Hair care	1.5 per cent expressed as etidronic acid		
		Soap	0.2 per cent expressed as etidronic acid		
65	Benzalkonium chloride (INN), bromide and saccharinate (eg. Cetalkonium chloride, Stearalkonium chloride, Cetearalkonium bromide)	Hair care products rinsed off after use	3 per cent calculated as benzalkonium chloride	In the finished product the concentration of benzalkonium chloride, bromide and saccharinate with an alkyl chain-length of C ₁₄ or less must not exceed 0.1 per cent calculated as	Avoid contact with the eyes

<i>(1)</i> <i>Reference</i> <i>number</i>	<i>(2)</i> <i>Name of</i> <i>substance</i>	<i>(3)</i> <i>Purpose of</i> <i>substance</i> <i>or type of</i> <i>product</i>	<i>(4)</i> <i>Maximum</i> <i>concentration</i> <i>of substance</i> <i>in product</i>	<i>(5)</i> <i>Other</i> <i>requirements</i>	<i>(6)</i> <i>Required</i> <i>information</i>
				benzalkonium chloride	
		Other products	0.1 per cent calculated as benzalkonium chloride		Avoid contact with the eyes
66	Polyacrylamides	Body-care leave-on products		Maximum residual acrylamide content 0.1 mg/kg	
		Other cosmetic products		Maximum residual acrylamide content 0.5 mg/kg	

PART 2

ENTRIES TO BE INSERTED AT THE END OF THE TABLE IN PART 1 OF SCHEDULE 4 TO THE PRINCIPAL REGULATIONS

<i>(1)</i> <i>Reference</i> <i>number</i>	<i>(2)</i> <i>Name of</i> <i>substance</i>	<i>(3)</i> <i>Purpose of</i> <i>substance</i> <i>or type of</i> <i>product</i>	<i>(4)</i> <i>Maximum</i> <i>concentration</i> <i>of substance</i> <i>in product</i>	<i>(5)</i> <i>Other</i> <i>requirements</i>	<i>(6)</i> <i>Required</i> <i>information</i>
96	1-tert-Butyl-3,5-dimethyl-2,4,6-trinitrobenzene (CAS No 81-15-2) (musk xylene)	All cosmetic products, with the exception of oral care products	1.0 per cent in fine fragrance 0.4 per cent in eau de toilette 0.03 per cent in other products		
97	4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	1.4 per cent in fine fragrance 0.56 per cent in eau de toilette		

Status: This is the original version (as it was originally made).

<i>(1)</i> <i>Reference</i> <i>number</i>	<i>(2)</i> <i>Name of</i> <i>substance</i>	<i>(3)</i> <i>Purpose of</i> <i>substance</i> <i>or type of</i> <i>product</i>	<i>(4)</i> <i>Maximum</i> <i>concentration</i> <i>of substance</i> <i>in product</i>	<i>(5)</i> <i>Other</i> <i>requirements</i>	<i>(6)</i> <i>Required</i> <i>information</i>
	(musk ketone)		0.042 per cent in other products		

PART 3

ENTRY TO BE SUBSTITUTED FOR ENTRY 5 IN PART 1 OF SCHEDULE 6 TO THE PRINCIPAL REGULATIONS

<i>(1)</i> <i>Reference</i> <i>number</i>	<i>(2)</i> <i>Name of</i> <i>substance</i>	<i>(3)</i> <i>Purpose of</i> <i>substance</i> <i>or type of</i> <i>product</i>	<i>(4)</i> <i>Maximum</i> <i>concentration</i> <i>of substance</i> <i>in product</i>	<i>(5)</i> <i>Other</i> <i>requirements</i>	<i>(6)</i> <i>Required</i> <i>information</i>
5	Formaldehyde and para-formaldehyde	For oral hygiene Except for oral hygiene (see also Part 1 of Schedule 4)	0.1 per cent (expressed as free formaldehyde) 0.2 per cent (expressed as free formaldehyde)	Not to be used in aerosol dispensers (sprays)	—

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 2004 (S.I.2004/2152) (“the Principal Regulations”).

The Principal Regulations implement Council Directive [76/768/EEC](#) (O.J. No. L262 27.9.1976, p.169) (“the Directive”) on the approximation of the laws of the Member States relating to cosmetic products (as amended). These Regulations implement Commission Directives [2004/87/EC](#) (O.J. No. L287, 8.9.2004, p.4), [2004/88/EC](#) (O.J. No. L287, 8.9.2004, p.5) and [2004/93/EC](#) (O.J. No. L300, 25.9.2004, p.13) which amend Annexes II and III to the Directive. They also correct errors in the Principal Regulations.

The main changes made to the Principal Regulations are as follows: regulation 2(2)(a) implements Directive [2004/93/EC](#) by replacing the prohibition on the use of substances classified as carcinogenic, mutagenic or toxic to reproduction (“CMR’s”). The new prohibition applies only

to CMR's listed in Annex II to the Directive. Regulation 2(5)(b) provides that no proceedings or enforcement action shall be taken in relation to the previous prohibition.

Regulations 2(8)(a)(iv) and 2(8)(b)(ii) implement Directive [2004/88/EC](#) by inserting and deleting various substances in Schedule 4 to the Principal Regulations.

Regulation 2(8)(b)(i) implements Directive [2004/87/EC](#) by postponing until 31st December 2005 the date until which the substances listed in Part 2 of Schedule 4 are permitted.

A regulatory impact assessment has not been produced for this instrument. A full regulatory impact assessment of the effect that the Principal Regulations will have on costs to business is available from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET. Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET.