
S T A T U T O R Y I N S T R U M E N T S

2000 No. 2765

CONSUMER PROTECTION

**The Cosmetic Products (Safety) (Amendment) (No. 2)
Regulations 2000**

<i>Made - - - - -</i>	<i>9th October 2000</i>
<i>Laid before Parliament</i>	<i>10th October 2000</i>
<i>Coming into force (except as provided in regulation 1(2) and (3) - - -</i>	<i>31st October 2000</i>

Whereas the Secretary of State is a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to measures for safety and consumer protection as regards cosmetic products and any provisions concerning the composition, labelling, marketing, classification or description of cosmetics products:

Now, therefore, the Secretary of State in exercise of the powers conferred on him by section 2(2) of that Act hereby makes the following Regulations:—

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) (No. 2) Regulations 2000 and, except as provided by paragraphs (2) and (3) below, shall come into force on 31st October 2000.

(2) Regulation 3 and this regulation shall come into force on 11th October 2000.

(3) Regulation 2(c)-(h) shall come into force on 1st January 2001.

2. The Cosmetic Products (Safety) Regulations 1996(c) (“the principal Regulations”) are amended as follows—

(a) in regulation 2(1), in the definition of “the Directive”, by deleting the word “and” before “Commission Directive 2000/41/EC”(d) and by adding words “, Commission Directive 2000/6/EC(e) and Commission Directive 2000/11/EC(f)” at the end of the definition;

(b) in Schedule 1, by the deletion of entry number 423, and

(c) in Part I of Schedule 2—

(a) S.I. 1972/1811, 1975/1707, 1993/2661.

(b) 1972 c. 68.

(c) S.I. 1996/2925, amended by S.I. 1997/2914, S.I. 1998/1727, S.I. 1999/1552 and S.I. 2000/1679.

(d) The reference to Commission Directive 2000/41/EC was added to S.I. 1996/2925 by S.I. 2000/1679.

(e) O.J. No. L56, 1.3.2000, p.42.

(f) O.J. No. L65, 14.3.2000, p.22.

(i) by the substitution for entry number 1 of the following—

“1a.	Boric acid, borates, and tetraborates	Talcum powder	5 per cent	Not to be used in products intended for children under three years old. Not to be used in products intended for peeling or irritated skin if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid.	Not to be used for bathing children under three years old. Do not use on peeling or irritated skin. (Only required if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid).
		Oral hygiene products	0.1 per cent	Not to be used in products intended for children under 3 years old.	Do not swallow. Not to be used for children under three years old.
		Other products (excluding bath products and hair waving products)	3 per cent	Not to be used in products intended for children under three years old. Not to be used in products intended for peeling or irritated skin if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid.	Not to be used for children under three years old. Do not use on peeling or irritated skin. (Only required if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid).
		The above-mentioned percentages are calculated as boric acid			
1b.	Tetraborates	Bath products	18 per cent	Not to be used in products for children under 3 years old.	Not to be used for bathing children under three years old.
		Hair waving products	8 per cent The above-mentioned percentage are calculated as boric acid		Rinse well”;

(ii) by the substitution for entry number 14 of the following—

“14	Hydroquinone	Oxidising colouring agent for hair dyeing for general use	0.3 per cent subject to the provisions of “Combination Rule B” set out below	—	Contains hydroquinone. Do not use to dye eye-lashes or eyebrows. Rinse eyes immediately if product comes into contact with them.
		Oxidising colouring agent for hair dyeing for professional use	0.3 per cent subject to the provisions of the “Combination Rule B” set out below	—	Contains hydroquinone. For professional use only. Rinse eyes immediately if product comes into contact with them”;

(iii) by the insertion after entry number 64 of the following—

“65	Benzalkonium chloride (INN), bromide and saccharinate (eg. Cetalkonium chloride, Stearalkonium chloride, Cetearalkonium bromide)	Hair care products rinsed off after use	3 per cent calculate 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 benzalkonium chloride.	Avoid contact with the eyes.
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Other products 0.1 per cent calculated as benzalkonium chloride Avoid contact with the eyes”;

(d) In Part I of Schedule 4 by adding the following entries after entry number 54(a)—

“55	Benzylhemi-formal	Products rinsed off after use	0.15 per cent	—	—
56	3-Iodoprop-2-ynyl butylcarbamate (Iodopropynyl butylcarbamate)	Not to be used in oral hygiene and lip products	0.05 per cent	—	Contains iodine (Only required where the 3-iodoprop-2-ynyl butylcarbamate concentration in products intended to remain on the skin exceeds 0.02 per cent)”;

(e) In Part II of Schedule 4, by the deletion of entry numbers 21 and 29;

(f) In Part I of Schedule 5, by adding the following entries after entry number 20(b)—

“21	2-Ethylhexyl 4-dimethylaminobenzoate [Octyl dimethyl PABA]	8 per cent	—	—
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzone (INN) and Sulisobenzone sodium (INN))	5 per cent (expressed as acid)	—	—
23	2-2'-Methylenebis[6-(2 <i>H</i> -benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]	10 per cent	—	—
24	<i>di</i> Sodium 2,2'-(1,4-phenylene)bis(1 <i>H</i> -benzimidazole-4,6-disulfonate)	10 per cent (expressed as acid)	—	—
25	5,5'-Bis(2-ethylhexyloxy)-2,2'-(6- <i>p</i> -methoxyphenyl-1,3,5-triazine-2,4-diyl)diphenol	10 per cent	—	—;”

(g) In Part II of Schedule 5, by the deletion of entry numbers 5, 17 and 29;

(h) In Schedule 5A(c), by the substitution for sub-paragraph (b)(ii) of the following—

“(ii) Transesterification or hydrolysis at a temperature of at least 200°C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters)”.

3.—(1) The following entries in Schedule 1 shall continue to have effect in relation to any supply of a cosmetic product to which regulation 4(2)(a) of the principal Regulations applies on or after 17th March 2000 but shall cease to have effect in relation to any such supply of cosmetic products occurring prior to that date and no investigation, legal proceeding or remedy may be instituted, continued or enforced, and no penalty, forfeiture or punishment may be imposed in respect of any such supply—

“2	Acetonitrile	—	393
9	Acetyletyltetramethyltetralin (AETT)	341	362
55	Anti-androgens with steroid structure	—	390
62	Aristolochic acid and its salts	—	365
208	Colouring agent CI 42640	—	386
341	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonephthone	9	362
399	11 α -Hydroxypregn-4-ene-3,20-dione and its esters	—	385
485	Minoxidil (INN), its salts and derivatives	596	372
587	<i>Phytolacca spp and their preparations</i>	—	374
596	6-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide, its salts and derivatives	485	372
688	2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin	—	367
697	Tetrahydrozoline and its salts	—	394
727	Tribromsalan (INN)	728	373
728	3,4',5-Tribromosalicylanilide	727	373

(a) Entry number 54 was added to S.I. 1996/2925 by S.I. 1999/1552.

(b) Entry number 20 was added to S.I. 1996/2925 by S.I. 1999/1552.

(c) Schedule 5A was added to S.I. 1996/2925 by S.I. 1998/1727.

766 Zirconium and its compounds (except aluminium zirconium chloride hydroxide complexes and 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 Schedule 3 by “*” immediately after the name or colour index number) — 391;”

(2) Entry number 749 of Schedule 1 shall be deleted.

Kim Howells,
Parliamentary Under-Secretary of State for Consumers and Corporate Affairs,
Department of Trade and Industry

9th October 2000

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 1996 (S.I. 1996/2925) (“the principal Regulations”).

Commission Directive 2000/11/EC amends for the twenty-fifth time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. In line with the judgement of the European Court of Justice of 25th January 1994, C-212/91 *Angelopharm GmbH v Freie Hansestadt Hamburg*, it removes from Annex II to Council Directive 76/768/EEC substances which had been improperly added to Annex II by Commission Directives 82/107/EEC, 84/415/EEC, 86/179/EEC, 87/137/EEC, 88/233/EEC and 90/121/EEC. The substances were added without proper consultation with the Scientific Committee on Cosmetic Products and Non-Food Products. Commission Directive 2000/11/EC then re-inserts these substances, with the exception of Tyrothricin (INN) back in Annex II to Council Directive 76/768/EEC with immediate effect.

The Regulations implement Commission Directive 2000/6/EC (which amended Council Directive 76/768/EEC for the twenty-fourth time) and 2000/11/EC by amending the principal Regulations to—

1. Permit subject to restrictions, the use of boric acid, borates, and tetraborates in talcum powder, oral hygiene products and other products (excluding bath products and hair waving products), and impose labelling requirements (in respect of products intended to be used for children under 3 years old and in respect of use on peeling or irritated skin). Also to permit, subject to restrictions the use of tetraborates in bath products and hair waving products and imposing labelling requirements in respect of products intended to be used for children under three years old (regulation 2(c)(i)).

2. Prohibit the use of hydroquinone as a skin lightener and reduce the level of hydroquinone in oxidation hair dyes (regulation 2(c)(ii)).

3. Permit, subject to restrictions, the use of Benzalkonium chloride, bromide and saccharinate in hair care products and other products and impose labelling requirements (regulation 2(c)(iii)).

4. Permit the use, subject to restrictions, of benzylhemiformal as a preservative in products which are rinsed off after use. Also to permit the use, subject to restrictions of 3-iodoprop-2-ynyl butylcarbamate [Iodopropynyl butylcarbamate] as a preservative though not to be used in oral hygiene and lip products (regulation 2(d)).

5. Permit, subject to restrictions, the use of 2-Ethylhexyl 4-dimethylaminobenzoate [Octyl dimethyl PABA]; 2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzone (INN) and Sulisobenzone sodium (INNM)); 2,2'-Methylenebis[6-(2*H*-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]; *di*Sodium 2,2'-(1,4-phenylene)bis(1*H*-benzimidazole-4,6-disulfonate); and 5,5'-bis(2-ethylhexyloxy)-2,2'-(6-*p*-methoxyphenyl-1,3,5-triazine-2,4-diyl)diphenol as UV filters in cosmetic products (regulation 2(f)).

6. Amending the methods by which tallow derivatives may be manufactured (regulation 2(h)).

7. Provide that as from the date of coming into force of the Regulations the following entries in Schedule 1 shall continue to have effect in relation to the supply of cosmetics on or after 17th March (the date Commission Directive 2000/11/EC came into force) but shall cease to have effect in relation to any supply of cosmetic products occurring prior to that date (regulation 3(1))—

2; 9; 55; 62; 208; 341; 399; 485; 587; 596; 688; 697; 727; 728; 766.

8. Delete entry number 749 (Tyrothricin (INN)) from the list of prohibited substances in Schedule 1 (regulation 3(2)). However the use of Tyrothricin (which is an antibiotic) in cosmetics will continue to be prohibited by entry number 56 which prohibits the use of antibiotics.

The Regulations also remove laurel oil of unspecified origin from Schedule 1 which had been incorrectly added (regulation 2(b)).

The Regulations come into force on 31st October 2000 except as provided by Regulation 1(2) and (3).

STATUTORY INSTRUMENTS

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