

STATUTORY INSTRUMENTS.

S.I. No. 852 of 2004.

EUROPEAN COMMUNITIES (DANGEROUS SUBSTANCES AND PREPARATIONS) (MARKETING AND USE) (AMENDMENT) REGULATIONS 2004.

I, MICHEÁL MARTIN, Minister for Enterprise, Trade and Employment in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Council Directive 76/769/EEC of 27 July 1976¹ as amended by Commission Directive 2003/3/EC of 6 January 2003², Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003³, Commission Directive 2004/21/EC of 24 February 2004⁴, Commission Directive 2004/96/EC of 27 September 2004⁵ and Commission Directive 2004/98/EC of 30 September 2004⁶, hereby make the following regulations:

⁶ O.J. No. L 305, 1.10.2004, p.63

⁵ O.J. No. L 301, 28.9.2004, p. 51

⁴ O.J. No. L 57, 25.2.2004, p.4

³ O.J. No. L 178, 17.7.2003, p.24

² O.J. No. L 4, 9.1.2003, p.12

¹ O.J. No. L 262, 27.9.1976, p.201

1. (1) These Regulations may be cited as the European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2004.

(2) The Principal Regulations, the Regulations of 2003 and these Regulations may be cited together as the European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations 2003 to 2004.

2. (1) In these Regulations—

"Principal Regulations" means the European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations 2003 (S.I. No. 220 of 2003) as amended by the European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2003 (S.I. No. 503 of 2003);

"Regulations of 2003" means the European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2003 (S.I. No. 503 of 2003).

(2) A word or expression that is used in these Regulations and is also used in Council Directive 76/769/EEC of 27 July 1976¹, Commission Directive 2003/3/EC of 6 January 2003², Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003³, Commission Directive 2004/21/EC of 25 February 2004⁴, Commission Directive 2004/96/EC of 27 September 2004⁵ and Commission Directive 2004/98/EC of 30

September 2004⁶ has, unless the contrary intention appears, the same meaning in these Regulations as in the Directive concerned.

⁶ O.J. No. L 305, 1.10.2004, p. 63

⁵ O.J. No. L 301, 28.9.2004, p. 51

⁴ O.J. No. L 57, 25.2.2004, p. 4

³ O.J. No. L 178, 17.7.2003, p. 24

² O.J. No. L 4, 9.1.2003, p. 12

¹ O.J. No. L 262, 27.9.1976, p. 201

(3) In these Regulations—

(a) a reference to a paragraph is to a paragraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended, and

(b) a reference to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

3. (1) Schedule 1 to the Principal Regulations is amended—

(a) by substituting the provisions set out in Schedule A for reference number 28,

(b) by substituting the provisions set out in Schedule B for reference numbers 43, 44 and 45, and

(c) by adding the provisions set out in Schedule C after reference number 45.

(2) Schedule 3 to the Principal Regulations is amended under the heading "point 43 (of Schedule 1) — Azocolourants" by substituting the provisions set out in Schedule D.

(3) Paragraphs (1)(b) and (2) shall come into operation on 31 December 2004.

(4) Paragraph (1)(c) shall come into operation on 17 January 2005.

(5) Paragraph (1)(a) shall come into operation on 1 September 2005.

4. Notwithstanding Regulation 3(1)(c), the validity of any existing national authorisations of pesticides or biocidal products containing nonylphenol ethoxylate (NPE) as a coformulant, which have been granted before 17 July 2003, shall not be affected by these Regulations until such authorisations expire.

Regulation 3(1)(a)

28. Directive No. 94/27/EC of the European Parliament and of the Council and Commission Directive 2004/96/EC

Nickel and its compounds CAS No. 7440-0-20 EINECS No. 231-111-4

The provisions at points 1, 2 and 3 below shall apply as follows:—

(a) From 20 July 2000 no manufacturer or importer may place on the market products which fail to comply with those provisions, and

(b) From 20 July 2001 products which fail to comply with those provisions may not be sold or made available to the final consumer unless they have been placed on the market before 20 January 2000.

Nickel and its compounds may not be used:

1. in all post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than $0.2 \mu\text{g}/\text{cm}^2/\text{week}$ (migration limit).

2. in products intended to come into direct and prolonged contact with the skin such as:

- earrings,
- necklaces, bracelets and chains, anklets, finger rings,
- wrist-watch cases, watch straps and tighteners,
- rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments

if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than $0.5 \mu\text{g}/\text{cm}^2/\text{week}$; (as measured by the method laid down in the harmonised CEN standard EN 1811:1998 "Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin", as published in Commission Communication 1999/C 205/05 of 20 July 1999).

3. in products such as those listed in point 2 where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ for a period of at least two years of normal use of the product (as measured by the method laid down in the harmonised CEN standard EN 12472:1998 "Method for the simulation of wear and corrosion for the detection of nickel release from coated items", as published in Commission Communication 1999/C 205/05 of 20 July 1999).

Regulation 3(1)(b)

43. Commission Directive No. 2003/3/EC and Commission Directive No. 2004/21/EC

Azocolourants (See lists of aromatic amines and azodyes in Schedule D to these Regulations.)

1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Schedule 3, in detectable concentrations, i.e.

above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing methods listed in Schedule 3, may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,
- footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,
- textile or leather toys and toys which include textile or leather garments,
- yarn and fabrics intended for use by the final consumer.

2. Furthermore, the textile and leather articles referred to in point 1 above may not be placed on the market unless they conform to the requirements set out in that point.

By way of derogation, until 1 January 2005, this provision shall not apply to textile articles made of recycled fibres if the amines are released by residues deriving from previous dyeing of the same fibres and if the listed amines are released in concentrations below 70 ppm.

3. Azodyes, which are contained in the "List of azodyes" set out in Schedule 3, may not be placed on the market or used for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0.1% by mass.

4. Not later than 11 September 2005, the Commission shall, in the light of new scientific knowledge, review the provisions on azocolourants.

44. Directive No. 2003/11/EC of the European Parliament and of the Council and Commission Directive 2004/98/EC
diphenylether, pentabromo derivative $C_{12}H_5Br_5O$

1. May not be placed on the market or used as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1% by mass

2. Articles may not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations higher than 0.1 % by mass.

3. By way of derogation, until 31 March 2006 paragraphs 1 and 2 shall not apply to aircraft emergency evacuation systems.

45. Directive No. 2003/11/EC of the European Parliament and of the Council
diphenylether, octabromo derivative $C_{12}H_2Br_8O$

1. May not be placed on the market or used as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1 % by mass.

2. Articles may not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations higher than 0.1 % by mass.

Regulation 3(1)(c)

46. Directive No. 2003/53/EC of the European Parliament and of the Council

(1) Nonylphenol $C_6H_4(OH)C_9H_{19}$

(2) Nonylphenol ethoxylate $(C_2H_4O)_n C_{15}H_{24}O$

May not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0.1 % by mass for the following purposes:

(1) industrial and institutional cleaning except:

— controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,

— cleaning systems with special treatment where the washing liquid is recycled or incinerated;

(2) domestic cleaning;

(3) textiles and leather processing except:

— processing with no release into waste water,

— systems with special treatment where the process water is pretreated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);

(4) emulsifier in agricultural teat dips;

(5) metal working except:

— uses in controlled closed systems where the washing liquid is recycled or incinerated;

(6) manufacturing of pulp and paper;

(7) cosmetic products;

(8) other personal care products except:

— spermicides;

(9) co-formulants in pesticides and biocides.

47. Directive No. 2003/53/EC of the European Parliament and of the Council
Cement

(1) Cement and cement-containing preparations may not be used or placed on the market, if they contain, when hydrated, more than 0.0002 % soluble chromium VI of the total dry weight of the cement.

(2) If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement-containing preparations shall be legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph (1).

(3) By way of derogation, paragraphs (1) and (2) shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing preparations are handled solely by machines and in which there is no possibility of contact with the skin.

Regulation 3(2)

Point 43 (of Schedule 1) — Azocolourants

List of aromatic names

	CAS number	Index number	EC number	Substances
		1		
	92-67-1			
	612-072-00-6			
	202-177-1			
	biphenyl-4-ylamine			
4-aminobiphenyl				
xenylamine				
		2		
	92-87-5			
	612-042-00-2			
	202-199-1			
	benzidine			

	3
95-69-2	
202-441-6	
4-chloro-o-toluidine	
	4
91-59-8	
612-022-00-3	
202-080-4	
2-naphthylamine	
	5
97-56-3	
611-006-00-3	
202-591-2	
o-aminoazotoluene	
4-amino-2',3-dimethylazobenzene	
4-o-tolylazo-o-toluidine	
	6
99-55-8	
202-765-8	
5-nitro-o-toluidine	
	7
106-47-8	
612-137-00-9	
203-401-0	
4-chloroaniline	
	8
615-05-4	
210-406-1	
4-methoxy-m-phenylenediamine	
	9
101-77-9	
612-051-00-1	
202-974-4	
4,4'-methylenedianiline	

4,4'-diaminodiphenylmethane	10
91-94-1	
612-068-00-4	
202-109-0	
3,3'-dichlorobenzidine	
3,3'-dichlorobiphenyl-4,4'-ylenediamine	11
119-90-4	
612-036-00-X	
204-355-4	
3,3'-dimethoxybenzidine	
o-dianisidine	12
119-93-7	
612-041-00-7	
204-358-0	
3,3'-dimethylbenzidine	
4,4'-bi-o-toluidine	13
838-88-0	
612-085-00-7	
212-658-8	
4,4'-methylenedi-o-toluidine	
	14
120-71-8	
204-419-1	
6-methoxy-m-toluidine	
p-cresidine	15
101-14-4	
612-078-00-9	
202-918-9	
4,4'-methylene-bis-(2-chloro-aniline)	

2,2'-dichloro-4,4'-methylene-dianiline	
	16
101-80-4	
202-977-0	
4,4'-oxydianiline	
	17
139-65-1	
205-370-9	
4,4'-thiodianiline	
	18
95-53-4	
612-091-00-X	
202-429-0	
o-toluidine	
2-aminotoluene	
	19
95-80-7	
612-099-00-3	
202-453-1	
4-methyl-m-phenylenediamine	
	20
137-17-7	
205-282-0	
2,4,5-trimethylaniline	
	21
90-04-0	
612-035-00-4	
201-963-1	
o-anisidine	
2-methoxyaniline	
	22
60-09-3	
611-008-00-4	
200-453-6	

4-amino azobenzene

List of azodyes

	CAS number
	Index number
	EC number
	Substances
	1
Not allocated	
Component 1:	
CAS-No.: 118685-33-9	
$C_{39}H_{23}ClCrN_7O_{12}S_2Na$	
611-070-00-2	
405-665-4	
A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)—1-naphtholato)(1-(5-chloro-2-oxidophenylazo)—2-naphtholato)chromate(1-);	
Component 2: $C_{46}H_{30}CrN_{10}O_{20}S_2.3Na$	
trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)	

List of testing methods

European Standardisation Organisation (*)

Reference and title of the standard

Reference document

Reference of the superseded standard

CEN

Leather — Chemical tests — Determination of certain azo colourants in dyed leathers

CEN ISO/TS

17234:2003

NONE

CEN

Textiles — Methods for the determination of certain aromatic amines derived from azo colourants — Part 1: Detection of the use of certain azo colourants accessible without extraction

EN 14362-1:2003

NONE

CEN

Textiles — Methods for determination of certain aromatic amines derived from azo colourants — Part 2: Detection of the use of certain azo colourants accessible by extracting the fibres

EN 14362-2:2003

NONE

(*) ESO: European Standardisation Organisations:

CEN: rue de Stassart 36, B-1050 Bruxelles; tel. (32-2) 550 08 11, fax: (32-2) 550 08 19.
<http://www.cenorm.be>

CENELEC: rue de Stassart 35, B-1050 Bruxelles; tel. (32-2) 519 68 71, fax: (32-2) 519 69 19.
<http://www.cenelec.org>

ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis; tel. (33) 492 94 42 00, fax: (33) 493 65 47 16. <http://www.etsi.org>



GIVEN under my Official Seal, 15th December 2004.

MICHEÁL MARTIN

Minister for Enterprise Trade and Employment.

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations amend Schedules 1 and 3 to the European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations, 2003 (S.I. No. 220 of 2003), as previously amended by the European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2003 (S.I. No. 503 of 2003).

The new Regulations transpose—

(i) Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003, which amends for the 26th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (nonylphenol, nonylphenol ethoxylate and cement),

(ii) Commission Directive 2004/21/EC of 24 February 2004, relating to restrictions on the marketing and use of "azo colourants" (thirteenth adaptation to technical progress of Council Directive 76/769/EEC),

(iii) Commission Directive 2004/96/EC of 27 September 2004 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress,

(iv) Commission Directive 2004/98/EC of 30 September 2004 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of pentabromodiphenyl ether in aircraft emergency evacuation systems for the purpose of adapting its Annex I to technical progress, and

(v) replace certain provisions of and retranspose other provisions of Commission Directive 2003/3/EC of 6 January 2003.

Directive 2004/96/EC is transposed through Regulation 3(1)(a) and Schedule A to these Regulations, which come into operation from 1 September 2005.

Directive 2004/21/EC is transposed through Regulation 3(1)(b) and (2), Schedule B, reference number 43, third column, point 1, and Schedule D, "Listing of testing methods", to these Regulations, which come into operation on 31 December 2004.

Directive 2003/53/EC is transposed through Regulation 3(1)(c) and Schedule C, to these Regulations, which come into operation on 17 January 2005.

The other provisions of Schedule B (third column, points 2 to 4) and Schedule D ("List of aromatic amines" and "List of azodyes"), to these Regulations, retranspose relevant provisions of Directive 2003/3/EC, which were first transposed through S.I. No. 503 of 2003.

Directive 2004/98/EC is transposed through Regulation 3(1)(b) and Schedule B to these Regulations, reference number 44, third column, point 3, which come into operation from 31 December 2004. Points 1 and 2 of the third column at reference number 44 retranspose relevant provisions of Directive 2003/11/EC, which were first transposed through S.I. No. 503 of 2003.

Reference number 45 of Schedule B to these Regulations retransposes relevant provisions of Directive 2003/11/EC, which were first transposed through S.I. No. 503 of 2003.