

COMMISSION DIRECTIVE 2003/3/EC

of 6 January 2003

relating to restrictions on the marketing and use of 'blue colourant' (twelfth adaptation to technical progress of Council Directive 76/769/EEC)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of dangerous substances and preparations ⁽¹⁾, as last amended by Commission Directive 2003/2/EC of 6 January 2003 relating to restrictions on the marketing and use of arsenic (tenth adaptation to technical progress to Council Directive 76/769/EEC) ⁽²⁾ and in particular Article 2(a) thereof, introduced by Council Directive 89/678/EEC ⁽³⁾,

Whereas:

- (1) Under Directive 76/769/EEC as amended by Directive 2002/61/EC of the European Parliament and the Council ⁽⁴⁾ specified azocolourants are not to be used in certain textiles and leather articles; nor may those textiles or leather articles be placed on the market unless they conform to the requirements in that directive.
- (2) The risks to the health and environment of 'blue colourant Index No 611-070-00-2' have been assessed under Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for the assessment of risks to health and the environment of substances notified in accordance with Council Directive 67/548/EEC ⁽⁵⁾; the risk assessment identified a need for reducing risks of the blue colourant to the environment as this blue colourant has a high aquatic toxicity, is not easily degradable and reaches the environment via waste water.
- (3) In order to protect the environment the placing on the market and the use of the blue colourant should be prohibited for colouring textile and leather articles. The blue colourant should therefore be added to those substances listed in Annex I to Directive 76/769/EEC.
- (4) The restrictions on the placing on the market and use of the blue colourant laid down by this Directive take into account the current state of knowledge and techniques regarding suitable alternatives.

- (5) This Directive should apply without prejudice to Community legislation laying down minimum requirements for the protection of workers, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽⁶⁾, and Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽⁷⁾, as last amended by Directive 1999/38/EC ⁽⁸⁾.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives on the removal of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is hereby adapted to technical progress as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2003 at the latest. They shall forthwith inform the Commission thereof. They shall apply these provisions as from 30 June 2004.

When Member States adopt those provisions, these shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

⁽¹⁾ OJ L 262, 27.9.1976, p. 201.

⁽²⁾ See page 9 of this Official Journal.

⁽³⁾ OJ L 398, 30.12.1989, p. 24.

⁽⁴⁾ OJ L 243, 11.9.2002, p. 15.

⁽⁵⁾ OJ L 227, 8.9.1993, p. 9.

⁽⁶⁾ OJ L 183, 29.6.1989, p. 1.

⁽⁷⁾ OJ L 196, 26.7.1990, p. 1.

⁽⁸⁾ OJ L 138, 1.6.1999, p. 66.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 January 2003.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

— In Annex I to Directive 76/769/EEC, point 43 is replaced by the following:

'43. Azocolourants	<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in the Appendix, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing method established in accordance with Article 2(a) of this Directive, 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:</p> <ul style="list-style-type: none"> — 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. <p>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.</p> <p>3. Azodyes, which are contained in the "List of azodyes" that is hereby added to the Appendix, 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.</p> <p>4. Not later than 11 September 2005, the Commission shall, in the light of new scientific knowledge, review the provisions on azocolourants.'</p>
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— The following point shall be added to the Appendix:

'Point 43 Azocolourants*List of aromatic amines*

	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

	CAS number	Index number	EC number	Substances
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 $C_{39}H_{23}ClCrN_7O_{12}S_2Na$ Component 2: $C_{46}H_{30}CrN_{10}O_{20}S_2 \cdot 3Na$	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-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)