OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS

CONCERNING

THE SAFETY REVIEW OF THE USE OF CERTAIN AZO-DYES IN COSMETIC PRODUCTS

adopted by the SCCNFP during the 19th plenary meeting
of 27 February 2002

1. Background

The input of the SCCNFP was requested concerning the review of the safety profile of four azo dyes (CI 12150, CI 20170, CI 26100 and CI 27290) that are currently approved for use in cosmetic products marketed in the EU.

The use of colorants in cosmetic products marketed in the EU is regulated through the provisions of Annex IV of Directive 76/768/EEC, 'List of colouring agents allowed for use in cosmetic products'. Only those materials which are listed in this Annex can be used in cosmetic products marketed in the EU, subject to the restrictions given in the listings.

The safety of these four azo-dyes has been questioned. The rationale for this review is on the basis that these colorants form carcinogenic amines during metabolism. The European Commission has been asked to revoke the positive listing of these colorants.

2. Mandate

It was requested that the SCCNFP reviewed the safety of the following azo dyes :

CI 12150, CI 20170, CI 26100 and CI 27290.

The SCCNFP was requested to give an opinion on the following questions :

* Does the safety profile of these four materials support their current positive listing under Annex IV of the cosmetics Directive 76/768/EEC and the subsequent utilisation of the colorants in cosmetic products under current uses and practices?

* Does the SCCNFP recommend additional restrictions on the use of these colorants in cosmetic products?

3. Opinion on the SCCNFP

This paper will focus only on mutagenicity and carcinogenicity (SCCNFP/0474/01) of the azo-dyes. Furthermore, this report is based on published literature.

3.1. Azo dyes

Azo compounds are by far the most widely used synthetic organic colorants. The Colour Index lists more than 2000 azo compounds. Azo dyes are generally synthesised starting from primary aromatic amines by diazotisation and coupling with e.g. phenols or secondary aromatic amines. The commercial products often contain high levels of other components, especially relevant from a toxicological point of view are aromatic amines as contaminants.

3.2. Mutagenicity of azo dyes

The genetic toxicology of some azo dyes has been reviewed (Combes, Haveland-Smith 1982). Structure-activity relationships were assessed (Chung, Cerniglia 1992, Chung et al. 2000). It has been demonstrated that sulphonated derivatives (aromatic aminosulphonic acids) generally have no or very low genotoxic potential (Jung et al. 1992). A protocol for testing azo dyes for mutagenic activity in *Salmonella typhimurium* was developed including the use of flavine mononucleotide rather than riboflavine and hamster liver S9 for metabolic activation (Prival, Mitchell 1982).

3.2 Carcinogenicity of azo dyes

Table 1 is a compilation of organic colorants which are recognised to be carcinogens. With the exception of 2 compounds all these colorants are azo dyes. Furthermore, in many European countries, e.g. in Germany, it is generally accepted that all azo dyes which may be split into carcinogenic aromatic amines are possible carcinogens and may not be used any more in consumer products (Technische Regeln für Gefahrstoffe, TRGS 614, Technical rules for hazardous substances). In its opinion on the risk of cancer caused by textiles and leather goods coloured with azo-dyes the CSTEE came to the conclusion that the concern from the point of view of carcinogenic risk should apply to all azo dyes which have the potential to undergo in vivo reduction to carcinogenic aromatic amines (CSTEE 1999).

3.3. Metabolism of azo dyes

The significance of azo-reduction in the mutagenesis and carcinogenesis of azo dyes is well established. In mammals, they are metabolised to the corresponding amines following incorporation. In the mammalian liver azo compounds are metabolised by cytosolic and microsomal enzymes, e.g. by reductive cleavage to the amines. The intestinal microflora plays an even more important role (e.g. Bartsch 1981, Chung 1983, Chung and Cerniglia 1992, Chung et al. 1992, Chung et al. 2000, Levine 1991).

The reductive cleavage of azo dyes during percutanous absorption was investigated *in vitro* using skin from mice, guinea pigs, and humans. All species tested were capable of reductive cleavage of the dyes (Collier et al. 1993). Following epicutaneous treatment of rats *in vivo* with a ^{14}C-labelled azo dye, a significant amount of radioactivity was found in urine and faeces. It was speculated that azo cleavage resulting in the formation of aromatic amines is mediated via the microflora of the rat skin (Aldrich 1986). Later on, it was demonstrated experimentally that various strains of human skin bacteria split a water soluble azo dye (direct blue 14) to the corresponding amine (o-tolidine) *in vitro* (Platzek et al. 1999).

Table 1 : List of organic colorants, recognised to be carcinogens

CI No.	Name	CAS No.	Source
-	All benzidine based azo dyes; 4,4'-diarylazobiphenyl dyes, with the exception of those specified elsewhere in Annex I to Directive 67/548/EEC	-	1999/43/EC Cat 2
10385	Acid Orange 3	6373-74-6	SCCNFP/0457/01
11000	Solvent Yellow 1	60-09-3	97/56/EC Cat 2
11020	Solvent Yellow 2	60-11-7	SCCNFP/0457/01
11160	Solvent Yellow 3	97-56-3	97/56/EC Cat 2
12075[1a]	Pigment Orange 5	3468-63-1	SCCNFP/0457/01
12100	Solvent Orange 2	2646-17-5	SCCNFP/0457/01
12120[2]	Pigment Red 3	2425-85-6	SCCNFP/0457/01
12156	Solvent Red 80	6358-53-8	SCCNFP/0457/01
15585[1b]	Pigment Red 53, Pigment Red 53:1, barium salt	2092-56-0, 5160-02-1	SCCNFP/0457/01
16150	Acid Red 26	3761-53-3	SCCNFP/0457/01
16155	Acid Dye	3564-09-8	SCCNFP/0457/01
22120	Direct Red 28	573-58-0	1999/43/EC Cat 2
22610	Direct Blue 6	2602-46-2	1999/43/EC Cat 2
23635	Acid Red 114	6459-94-5	SCCNFP/0457/01
23850	Direct Blue 14	72-57-1	ETAD[3]
23860	Direct Blue 53	314-13-6	SCCNFP/0457/01
24400	Direct Blue 15	2429-74-5	SCCNFP/0457/01
24401	Direct Blue 218	28407-37-6	SCCNFP/0457/01
30145	Direct Brown 95	16071-86-6	94/60/EC Cat 2
30235	Direct Black 38	1937-37-7	1999/43/EC Cat 2
42500[4]	Basic Red 9	479-73-2	SCCNFP/0457/01
42500[4]	Basic Red 9, hydrochloride	569-61-9	SCCNFP/0457/01
64500[5]	Disperse Blue 1	2475-45-8	SCCNFP/0457/01
77603[6]	Pigment Yellow 34	1344-37-2	SCCNFP/0457/01
77605[6]	Pigment Red 104	12656-85-8	SCCNFP/0457/01

[1a] Cosmetics directive Annex II No. 397 Colouring agents CI 12075 and its lakes, pigments and salts
[1b] Cosmetics directive Annex II No. 401 Colouring agent CI 15585
[2] Cosmetics directive Annex IV
[3] Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
[4] arylmethane
[5] anthrachinone
[6] 97/56/EC toxic for reproduction category 1 (additional classification)

3.4. Metabolism, mutagenicity and carcinogenicity of aromatic amines (arylamines)

The metabolism of arylamines has been studied intensively. Ring oxidation, N-glucuronidation, N-acetylation, and N-oxidation are the major metabolic pathways of arylamines in mammals, the latter being the crucial step of biotoxification. The enzymes involved are cytochrom P450 (CYP1A2 and CYP3A4, respectively), yielding N-hydroxylarylamines which are further glucuronidated in the liver or acetylated in the bladder. From these precursors in the acidic pH of the bladder, nitrenium ions are formed which have been demonstrated to react with the DNA base guanine. In humans there are toxicologically important individual polymorphisms of the slow N-acetyltransferase 2 (NAT2) and of the CYP leading to differing individual susceptibilities with regard to human bladder carcinogenesis (Marquardt et al. 1999).

The majority of the arylamines is mutagenic, especially in the Salmonella tester strains TA98 and TA100, but metabolic activation with the S9 microsomal preparation mix is required for activity for most of the compounds.

Epidemiological studies have provided evidence for at least some aromatic amines as being human carcinogens: benzidine and 2-naphthylamine were shown to induce urinary bladder cancers in workers in the azo-dye industry (IARC 1975, 1982). 4-Aminobiphenyl (CAS 92-67-1), benzidine (CAS 92-87-5) and 2-naphthylamine (91-59-8) are classified as carcinogens of category 1 in the EU while 4-chloro-o-toluidine (CAS 95-69-2) is classified only in Germany as category 1 carcinogen (see Table 2).

In the EU, the following amines are classified as carcinogens of category 2: o-Aminoazotoluene (CAS 97-56-3), 4-chloroaniline (CAS 106-47-8), 4,4'-methylenedianiline (4,4´-diamino-diphenylmethane, CAS 101-77-9), 3,3´-dichlorobenzidine (CAS 91-94-1), 3,3´-dimethoxybenzidine (CAS 119-90-4), 3,3´-dimethylbenzidine (CAS 119-93-7), 4,4'-methylenedi-o-toluidine (3´-dimethyl-4,4´-diaminodiphenylmethane, CAS 838-88-0), 4,4´-methylene-bis-(2-chloroaniline) (CAS 101-14-4), o-toluidine (CAS 95-53-4), 4-methyl-m-phenylenediamine (2,4´-toluylenediamine, CAS 95-80-7), o-anisidine (2-methoxyaniline, CAS 90-04-0), 4-aminoazobenzene (CAS 60-09-3), 4-amino-3-fluorophenol (CAS 399-95-1).

In Germany in addition the following amines are classified as carcinogens of category 2: 5-nitro-o-toluidine (2-amino-4-nitrotoluene, CAS 99-55-8), 4-methoxy-m-phenylenediamine (2,4-diaminoanisole, CAS 615-05-4), 6-methoxy-m-toluidine (p-cresidine, CAS 120-71-8), 4,4´-oxydianiline (CAS 101-80-4), 4,4´-thiodianiline (CAS 139-65-1), 2,4,5-trimethylaniline, (CAS 137-17-7), 6-amino-2-ethoxynaphthaline (CAS 293733-21-8). 2,4-xylidine (CAS 95-68-1) and 2,6-xylidine (2,6-dimethylaniline, CAS 87-62-7) are classified as carcinogens of category 3 corresponding to chemical law whereas in the German List of MAK and BAT Values they are classified as carcinogens of category 2.

Recently, a draft for the risk assessment report of o-anisidine was prepared (CSTEE 2000). With regard to carcinogenicity the authors concluded that o-anisidine was carcinogenic in rats and mice. In both species, the main target organ is the urinary bladder. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has evaluated the report. In its opinion the committee agreed with the overall conclusion of the risk assessment (CSTEE 2001).

3.5. European regulations

According to the directive 1999/43/EC (17th amendment of directive 76/769/EEC) all benzidine based azo dyes as well as the azo dyes Direct Red 28 (CI 22120, CAS 573-58-0), Direct Blue 6 (CI 22610, CAS 2602-46-2) and Direct Black 38 (CI 30235, CAS 1937-37-7) are classified as carcinogens of category 2 (EEC 1999). According to the directive 97/56/EC (16th amendment of directive 76/769/EEC) Solvent Yellow 1 (CI 11000, 4-aminoazobenzene, CAS 60-09-3) and Solvent Yellow 3 (CI 11160, CAS 97-56-3) are classified as carcinogenic of category 2 (EEC 1997). Direct Brown 95 (CI 30145, CAS 16071-86-6) was classified carcinogenic of category 2 by the directive 94/60/EC (14th amendment of directive 76/769/EEC (EEC 1994)).

It was proposed to amend the directive 76/769/EEC with restrictions on certain azo-colorants :

Azo-dyes that may release, by reductive cleavage of one or more azo groups, one or more of the aromatic amines listed in Appendix, in concentrations above 30 ppm in the finished articles, according to the testing method specified in Appendix, may not be used in textile and leather articles which have the potential of coming into direct and prolonged contact with the human skin or oral cavity. (EEC 2000). The respective amines are listed in Table 2, Nos 1-21.

Table 2 : List of aromatic amines with carcinogenic potential

Number	CAS-No.	Name	EU class
1	92-67-1	4-Aminobiphenyl	CA cat 1
2	92-87-5	Benzidine	CA cat 1
3	95-69-2	4-Chloro-o-toluidine	CA cat 1 [a]
4	91-59-8	2-Naphthylamine	CA cat 1
5	97-56-3	o-Aminoazotoluene	CA cat 2
6	99-55-8	5-Nitro-o-toluidine (2-Amino-4-nitrotoluene)	CA cat 2 [a]
7	106-47-8	4-Chloroaniline	CA cat 2
8	615-05-4	4-Methoxy-m-phenylenediamine (2,4-Diaminoanisole)	CA cat 2 [a]
9	101-77-9	4,4'-Methylenedianiline (4,4´-Diamino-diphenylmethane)	CA cat 2
10	91-94-1	3,3´-Dichlorobenzidine	CA cat 2
11	119-90-4	3,3´-Dimethoxybenzidine	CA cat 2
12	119-93-7	3,3´-Dimethylbenzidine	CA cat 2
13	838-88-0	4,4'-Methylenedi-o-toluidine (3´-Dimethyl-4,4´-diaminodiphenylmethane)	CA cat 2
14	120-71-8	6-Methoxy-m-toluidine (p-Cresidine)	CA cat 2 [a]
15	101-14-4	4,4´-Methylene-bis-(2-chloroaniline)	CA cat 2
16	101-80-4	4,4´-Oxydianiline	CA cat 2 [a]
17	139-65-1	4,4´-Thiodianiline	CA cat 2 [a]
18	95-53-4	o-Toluidine	CA cat 2
19	95-80-7	4-Methyl-m-phenylenediamine (2,4´-Toluylenediamine, 2,4-toluenediamine)	CA cat 2
20	137-17-7	2,4,5-Trimethylaniline	CA cat 2 [a]
21	90-04-0	o-Anisidine (2-Methoxyaniline)	CA cat 2
22	60-09-3	4-Aminoazobenzene	CA cat 2
23	399-95-1	4-Amino-3-fluorophenol	CA cat 2
24	293733-21-8	6-Amino-2-ethoxynaphthaline	CA cat 2 [a]
25	95-68-1	2,4-Xylidine	CA cat 3 [a]
26	87-62-7	2,6-Xylidine (2,6-Dimethylaniline)	CA cat 3 [a]

[a] Category 2 in the German List of MAK and BAT Values

3.6. List of azo dyes based on carcinogenic arylamines (Annex 3)

Annex 3 Tables 1 – 5 gives further information on the dyes which can be split into carcinogenic amines (source: Verband der Chemischen Industrie, Association of the German Chemical Industry, VCI). Annex 3 Table 1 shows the azo dyes which are split into carcinogenic amines corresponding to the German Ordinance on Commodities (Bedarfsgegenständeverordnung, BGVO), available on the world market whereas substances listed in Table 2 of Annex 3 are not available. Annex 3 Table 3 is a list of azo dyes which are split into carcinogenic amines not included in the German BGVO, available on the world market whereas Annex 3 Table 4 substances are not available. Table 5 of Annex 3 is a list of azo dyes which are split into the carcinogenic amines 2,4-xylidine or 2,6-xylidine.

Colouring agent CI 12150

Primary name

CI 12150

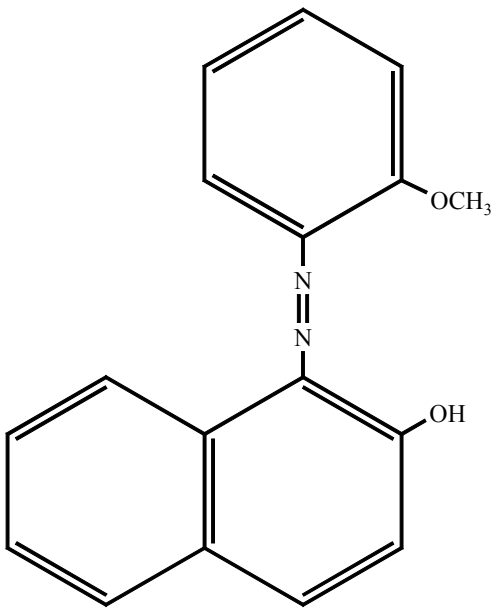
Chemical names

CI Solvent Red 1
CI Food Red 16
1-(o-Anisylazo)-2-naphthol
Sudan Rot G
1-((2-Methoxyphenyl)azo)-2-naphthol

Registry numbers

CAS : 1229-55-6
EINECS : 214-968-9

Structural formula



Empirical formula

Emp. Formula : $C_{17}H_{14}N_2O_2$
Mol weight : 278.3

Purity, composition and substance codes

There is no data available. Generally, azo dyes are known to be contaminated with the corresponding starting materials of their synthesis, in this case o-anisidine and 2-naphthol may be present.

Function and uses

CI 12150 is used in hair dyes (Blue List 2000). CI 12150 is listed in Annex IV Part 1 of the cosmetics directive 76/768/EEC, with the following field of application: Column 1: Colouring agents allowed in all cosmetic products. No other limitations and requirements are indicated.

Evaluation

Genotoxicity testing was negative in the Ames test using the "complete azo dye protocol" as outlined by Prival and Mitchell in 1982. Negative results were also obtained with regards to the induction of chromosome aberrations in CHO cells (Brooks et al. 1989). Using a mouse lymphoma assay the compound was found mutagenic following exogenous activation (Harrington-Brock et al. 1991). CI 12150 may release, by reductive cleavage of one or more azo groups, o-anisidine which is classified as carcinogen of category 2 in the EU.

Colouring agent CI 20170

Primary name

CI 20170

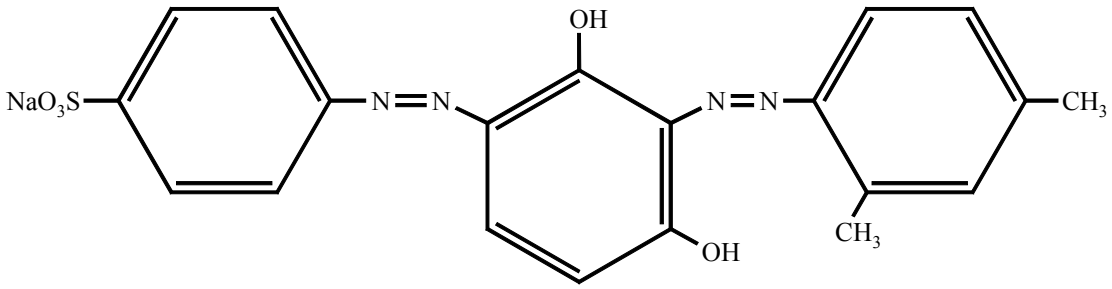
Chemical names

CI Acid Orange 24
4-((3-((Dimethylphenyl)azo)-2,4-dihydroxyphenyl)azo)-benzolsulfonsäure, Natriumsalz
Benzenesulfonic Acid, 4-[[3-[(Dimethylphenyl)Azo]-2,4-Dihydroxyphenyl]Azo]-, Monosodium Salt
4-[[3-[(2,4-Dimethylphenyl)Azo]-2,4-Dihydroxyphenyl]Azo]Benzenesulfonic Acid, Monosodium Salt
4-[3-(2,4-Dimethylphenylazo)-2,4-Dihydroxyphenylazo]Benzonsulfonsäure, Natriumsalz;
D&C Brown No. 1
C-Ext. Braun 4
Resorcin Braun
Brown No. 201

Registry numbers

CAS : 1320-07-6
EINECS : 215-296-9

Structural formula



Empirical formula

Emp. Formula : $C_{20}H_{18}N_4O_5S.Na$
Mol weight : 448.4

Purity, composition and substance codes

There is no data available. Generally, azo dyes are known to be contaminated with the corresponding starting materials of their synthesis, in this case resorcine, sulfanilic acid, 2,4- and 2,6-xylidine may be present.

Function and uses

CI 20170 is used in hair dyes (Blue List 2000). CI 20170 is listed in Annex IV Part 1 of the cosmetics directive 76/768/EEC, with the following field of application: Column 3: Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes. No other limitations and requirements are indicated.

Evaluation

CI 20170 was not mutagenic in the standard Ames test (Muzzall and Cook 1979). But no conclusion should be drawn from the negative test result since the metabolic activation conditions are not adequate (no Prival protocol). A chronic toxicity/carcinogenicity study (lifetime skin painting on female mice, negative outcome) performed in 1967 by American Cyanamid Company was cited (DFG 1991). CI 20170 may release, by reductive cleavage of one or more azo groups, 2,4-xylidine and 2,6-xylidine which are classified as carcinogens of category 3 corresponding to chemical law whereas in the German List of MAK and BAT Values they are classified as carcinogens of category 2.

Colouring agent CI 26100

Primary name

CI 26100

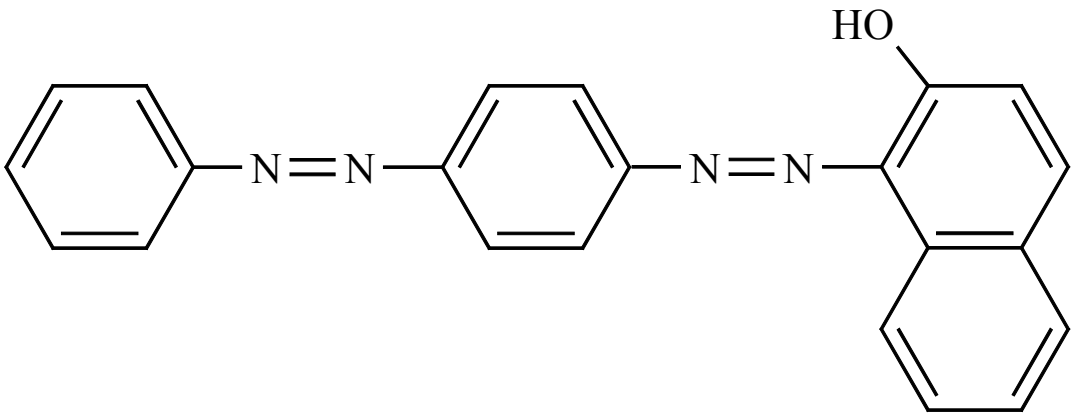
Chemical names

CI Solvent Red 23
1-[(4-Benzolazo)-benzolazo]-2-naphthol
D&C Red No. 17
Sudan III
Sudan Red BK
Ölrot 3G
C-Ext. Rot 56
Benzeneazobenzeneazo-beta-naphthol
1-((4-(Phenylazo)phenyl)azo)-2-naphthalenol
1-((p-Phenylazo)phenyl)azo-2-naphthol

Registry numbers

CAS : 85-86-9
EINECS : 201-638-4

Structural formula



Empirical formula

Emp. Formula : $C_{22}H_{16}N_4O$
Mol weight : 352.4

Purity, composition and substance codes

There is no data available. Generally, azo dyes are known to be contaminated with the corresponding starting materials of their synthesis, in this case purity criteria is set in the cosmetics directive (see below Function and uses).

Function and uses

CI 26100 is used in hair dyes (Blue List 2000). CI 26100 is listed in Annex IV Part 1 of the cosmetics directive 76/768/EEC, with the following field of application: Column 2: Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover. Other limitations and requirements are indicated: Purity criteria:
aniline ≤ 0.2 %, 2-naphthol ≤ 0.2 %, 4-aminoazobenzene ≤ 0.1 %, 1-(phenylazo)-2-naphthol ≤ 3 %, 1-[2-(phenylazo) phenylazo]-2-naphthalenol ≤ 2 %.

Evaluation

CI 26100 was tested for mutagenicity in the Ames test. 3 out of 5 commercial samples were mutagenic to *Salmonella typhimurium* strains TA98 and TA100 in the presence of S9 mix, the purified dye, however, was not mutagenic. The mutagenic activity was assigned by the authors to the contamination with 4-aminoazobenzene (starting material of the synthesis) (Miyagoshi et al. 1985). But no conclusion should be drawn from the negative test result since the metabolic activation conditions are not adequate (no Prival protocol).

The clastogenic potential of CI 26100 was investigated *in vitro* using CHO cells without metabolic activation. Although no metabolic activation system was added to the culture the number of breaks per metaphase was increased following addition of CI 26100 (Au and Hsu 1979).

The carcinogenic potential of CI 26100 was investigated following oral administration via food as a 1 % oil solution at the rate of 2 mg/animal/day to 83 male and 54 female mice. The authors did not consider the number of lung tumours to be significantly greater than in controls, due to the heterogeneous background of the mice. Groups of each 5 male and female Wistar rats were fed a diet containig 40,000 mg Sudan III per kg of diet for 18 months. No tumours were observed but no individual data on survival were given. No tumours were observed in 2 groups of 10 female mice given repeated s.c. injections of 0.25 ml of a saturated solution of CI 26100 in lard or about 5 mg of crystals injected subcutaneously. The working group of IARC considered these experiments as inadequate (IARC 1975). In 2 experiments using young adult female Long-Evans rats, CI 26100 was tested for possible carcinogenicity. In the first experimental set 0.5 ml of a 0.5 % (wt/vol) solution in sesame oil was injected in thigh muscle of both legs of 8 rats, age 27 days. At necropsy on day 276 no tumours were present. In the second experiment a group of 16 female rats was fed by gastric instillation 1 ml of a 0.1 % (wt/vol) 5 times a week for 25 weeks. At necropsy there were no tumours found (Huggins et al. 1978). Skin painting studies in 100 (50 male/50 female) Swiss Webster mice were carried out by administering 0.1 ml of a 1 % suspension of CI 26100 in an 1 % aqueous solution of sodium lauryl sulfate to the depilated skin (area 6 cm^2) once weekly for 18 months. No significant differences in body weight changes and survival as well as tumour incidences compared to the control group were found (Carson 1984).

It is worth mentioning that CI 26100 is a strong inducer of phase I and II drug metabolizing enzymes (mainly CYP1A and GST) which was shown to underly the protective effect against genotoxicity of 7,12-dimethylbenzanthracene (Ito et al. 1982, Ito et al. 1984, Hatakeyama et al. 1986), benzene (Fujie et al. 1992) and benzo(a)pyrene (Fujita et al. 1988). The 7,8,12-trimethylbenz[a]anthracene-induced leukemia in rats was prevented by combined treatment with CI 26100 probably by the same mechanism (Huggins et al. 1978).

CI 26100 may release, by reductive cleavage of one or more azo groups, 4-aminoazobenzene which is classified as carcinogen of category 2 in the EU.

Colouring agent CI 27290

Primary name

CI 27290

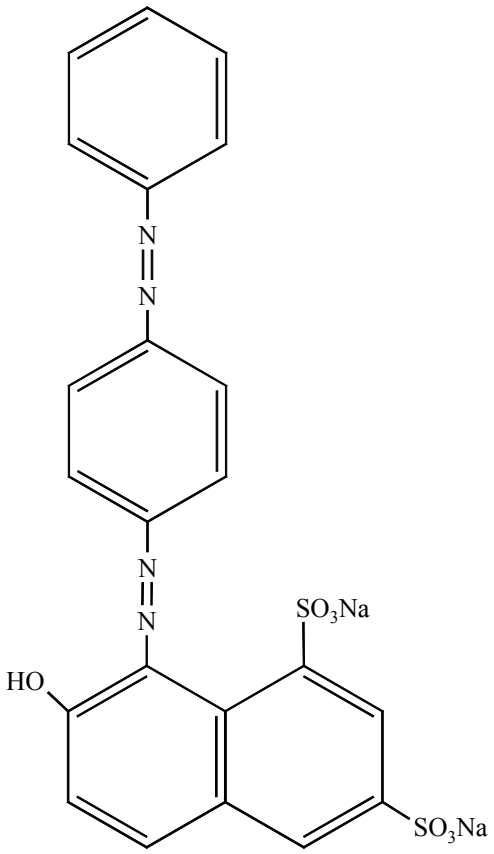
Chemical names

Sodium 6-hydroxy-5-(4-phenylazophenylazo)naphthalene-2,4-disulphonate
CI Acid Red 73
CI Solvent Red 69
D&C Red No. 13, Ext.
Baumwollscharlach extra
Brilliant Crocein MOO
7-Hydroxy-8-((4-(phenylazo)phenyl)azo)-1,3-naphthalindisulfonsäure, Dinatriumsalz
1,3-Naphthalenedisulfonic Acid, 7-Hydrooxy-8-[[4-(Phenylazo)Phenyl]Azo]-, Disodium Salt

Registry numbers

CAS : 5413-75-2
EINECS : 226-502-1

Structural formula



Empirical formula

Emp. Formula : $C_{22}H_{16}N_4O_7S_2.2Na$

Purity, composition and substance codes

There is no data available. Generally, azo dyes are known to be contaminated with the corresponding starting materials of their synthesis, in this case 4-aminoazobenzene and 7-hydroxy-1,3-naphthalinesulfonic acid may be present.

Function and uses

CI 27290 is used in hair dyes (Blue List 2000). CI 27290 is listed in Annex IV Part 1 of the cosmetics directive 76/768/EEC, with the following field of application: Column 4: Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin. In a footnote it is mentioned that the insoluble barium, strontium and zirconium lakes, salts and pigments of this colouring agent shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 8. No other limitations and requirements are indicated.

Evaluation

CI 27290 may release, by reductive cleavage of one or more azo groups, 4-aminoazobenzene which is classified as carcinogen of category 2 in the EU.

3.7. Conclusion

The azo dyes CI 12150, CI 20170, CI 26100, and CI 27290 are expected to be cleaved into the carcinogenic amines o-anisidine (CI 12150), 2,4- and 2,6-xylidine (CI 20170), and 4-aminoazobenzene (CI 26100 and CI 27290). Following application onto the skin this might take place on the surface of the skin mediated by skin bacteria, during percutaneous absorption within the skin, and systemically in the liver but there is no data available. Furthermore, there is no data available on the amount of percutaneous absorption of the mentioned dyes. The published data on genotoxicity is incomplete and does not rule out a genotoxic potential of the dyes. Carcinogenicity was investigated only with CI 26100 but the studies were inadequate. Purity criteria exist only for CI 26100 (Annex IV of the cosmetics directive). Generally, azo dyes are known to be contaminated with the respective starting materials, in the case of CI 1250, CI 20170 and CI 27290 o-anisidine, 2,4- and 2,6-xylidine, and 4-aminoazobenzene may be present, respectively, which are known carcinogens (see Table 2). Considering the scarce data on purity, toxicology and exposure no risk assessment can be performed for the mentioned dyes. But, from the available literature on the chemical class of azo dyes it can be deduced that all azo dyes which are split into carcinogenic arylamines are possible carcinogens.

3.8. Opinion

The SCCNFP is of the opinion that based on the available information the use of the colorants CI 12150, CI 20170, CI 27290, CI 26100 and of other azo dyes which may release one or more carcinogenic aromatic amines, poses a risk to the health of the consumer.

3.9 References

1. Aldrich FD. (1986) Excretion of radioactivity from rats and rabbits following cutaneous application of two ^{14}C-labeled azo dyes. J Toxicol Environ Health 18: 347-355.
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Annex 1

Basic data on the amines 4-aminoazobenzene, o-anisidine, 2,4-xylidine, and 2,6-xylidine

4-Aminoazobenzene

Primary name

4-Aminoazobenzene

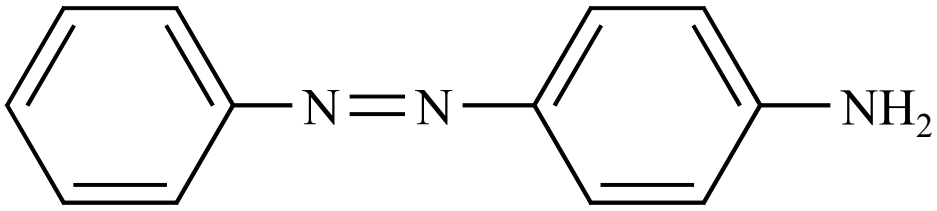
Chemical names

CI Solvent Yellow 1
CI 11000
p-Aminoazobenzene
4-(Phenylazo) benzenamine

Registry numbers

CAS : 60-09-3
EINECS : 200-453-6

Structural formula



Empirical formula

Emp. Formula : $C_{12}H_{11}N_3$
Mol weight : 197.2

Evaluation

4-Aminoazobenzene is classified as carcinogen of category 2 in the EU.

o-Anisidine

Primary name

o-Anisidine

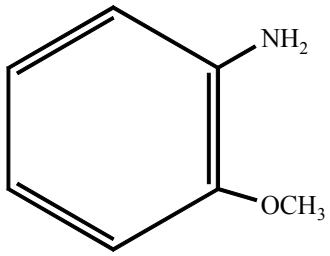
Chemical names

1-Amino-2-methoxy-benzene
2-Methoxyaniline
2-Aminoanisole

Registry numbers

CAS : 90-04-0
EINECS : 201-963-1

Structural formula



Empirical formula

Emp. Formula : C_7H_9NO
Mol weight : 123.16

Evaluation

o-Anisidine is classified as carcinogen of category 2 in the EU.

2,4-Xylidine

Primary name

2,4-Xylidine

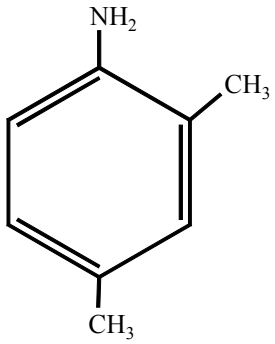
Chemical names

m-Xylidine
2,4-Dimethylaniline
1-Amino-2,4-dimethylbenzene
4-Amino-1,3-dimethylbenzene
2-Methyl-p-toluidine
2,4-Dimethylbenzenamine
2,4-Dimethylphenylamine

Registry numbers

CAS : 95-68-1
EINECS : 202-440-0

Structural formula



Empirical formula

Emp. Formula : $C_8H_{11}N$
Mol weight : 121.18

Evaluation

2,4-Xylidine is classified as carcinogen of category 2 in Germany.

2,6-Xylidine

Primary name

2,6-Xylidine

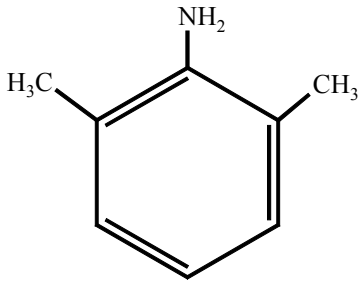
Chemical names

2,6-Dimethylaniline
2,6-Dimethylbenzenamine
o-Xylidine
1-Amino-2,6-dimethylbenzene
2-Amino-1,3-dimethylbenzene
2-Amino-m-xylene
2-Amino-1,3-xylene
2,6-Xylylamine

Registry numbers

CAS : 87-62-7
EINECS : 201-758-7

Structural formula



Empirical formula

Emp. Formula : $C_8H_{11}N$
Mol weight : 121.18

Evaluation

2,6-Xylidine is classified as carcinogen of category 2 in Germany.

Annex 2

Aromatic amines and colouring agents in Annex II of the directive 76/768/EEC

No. 22	Aniline, its salts and its halogenated and sulphonated derivatives (see Dossier Table 2 No. 7)
No. 26	Benzidine (see Dossier Table 2 No. 2)
No. 32	Toluidines, their isomers, salts and halogenated and sulphonated derivatives (see Dossier Table 2 No. 3 and 18)
No. 33	Xylidines, their isomers, salts and halogenated and sulphonated derivativesa
No. 81	4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride) (not in Dossier Table 2)
No. 242	1- and 2-Naphthylamines and their salts (see Dossier Table 2 No. 4)
No. 363	o-Phenylenediamine and its salts (not in Dossier Table 2)
No. 364	4-Methyl-m-phenylenediamine (see Dossier Table 2 No. 19)
No. 376	1-Methoxy-2,4-diaminobenzene (2,4-Diaminoanisole - CI 76050) and their salts (see 4-Methoxy-m-phenylenediamine Dossier Table 2 No. 8)
No. 377	1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and their salts (not in Dossier Table 2)
No. 378	Colouring agent CI 12140 (derived from amine 2,4-xylidine see Dossier Table 2 No. 25)
No. 379	Colouring agent CI 26105 (derived from amine o-toluidine see Dossier Table 2 No. 18)
No. 380	Colouring agent CI 42551, CI 42551-1, CI 42551-2 (not an azo dye, arylmethane)
No. 383	2-Amino-4-nitrophenol (not in Dossier Table 2)
No. 384	2-Amino-5-nitrophenol (not in Dossier Table 2)
No. 386	Colouring agent CI 42640 (not an azo dye, arylmethane)
No. 387	Colouring agent CI 13065 (azo dye, amine not in Dossier Table 2)
No. 388	Colouring agent CI 42535 (not an azo dye, arylmethane)
No. 389	Colouring agent CI 61554 (not an azo dye, anthraquinone)
No. 397	Colouring agents CI 12075 and its lakes, pigments and salts (amine 2,4-dinitroaniline not in Dossier Table 2)
No. 398	Colouring agent CI 45170 and CI 45170:1 (not an azo dye, xanthene)
No. 401	Colouring agent CI 15585 (amine not in Dossier Table 2)
No. 406	4-Ethoxy-m-phenylenediamine and its salts (not in Dossier Table 2)
No. 412	4-Amino-2-nitrophenol (not in Dossier Table 2)
No. 413	2-Methyl-m-phenylenediamine (not in Dossier Table 2)

Annex 3

Table 1 : Azo dyes which are split into carcinogenic amines corresponding to the German Bedarfsgegenständeverordnung, available on the world market

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
1	-	Acid Black 29	Benzidine
2	-	Acid Black 209	3,3'-Dimethylbenzidine (o-Tolidine)
3	30 334	Acid Black 232	Benzidine
4	30 336	Acid Black 94	Benzidine
5	22 195	Acid Orange 45	Benzidine
6	26 420	Acid Red 104	o-Aminoazotoluene, o-Toluidine
7	23 635	Acid Red 114	3,3'-Dimethylbenzidine (o-Tolidine)
8	27 200	Acid Red 115	o-Aminoazotoluene, o-Toluidine
9	-	Acid Red 119:1	p-Chloroaniline
10	24 125	Acid Red 128	3,3'-Dimethoxybenzidine (o-Dianisidine)
11	26 665	Acid Red 148	o-Aminoazotoluene, o-Toluidine
12	20 530	Acid Red 158	o-Toluidine
13	-	Acid Red 167	3,3'-Dimethylbenzidine (o-Tolidine)
14	16 140	Acid Red 24	o-Toluidine
15	18 129	Acid Red 265	o-Toluidine
16	18 065	Acid Red 35	o-Toluidine
17	22 245	Acid Red 85	Benzidine
18	37 085	Azoic Diazo Component 11	4-Chloro-o-toluidine
19	37 105	Azoic Diazo Component 12	2-Amino-4-nitrotoluene
20	37 235	Azoic Diazo Component 48	3,3'-Dimethoxybenzidine (o-Dianisidine)
21	37 225	Azoic Diazo Component 112	Benzidine
22	-	Azoic Diazo Component 113	3,3'-Dimethylbenzidine (o-Tolidine)
23	21 010	Basic Brown 4	2,4-Toluylendiamine
24	-	Basic Yellow 103	4,4'-Diaminodiphenylmethane
25	76 035	Developer 14 = Oxidation Base 20	2,4-Toluylendiamine
26	-	Direct Black 154	3,3'-Dimethylbenzidine (o-Tolidine)
27	22 580	Direct Black 29	Benzidine
28	30 235	Direct Black 38	Benzidine
29	30 245	Direct Black 4	Benzidine
30	24 410	Direct Blue 1	3,3'-Dimethoxybenzidine (o-Dianisidine)
31	22 590	Direct Blue 2	Benzidine
32	23 705	Direct Blue 3	3,3'-Dimethylbenzidine (o-Tolidine)
33	22 610	Direct Blue 6	Benzidine
34	24 140	Direct Blue 8	3,3'-Dimethoxybenzidine (o-Dianisidine)
35	24 155	Direct Blue 9	3,3'-Dimethoxybenzidine (o-Dianisidine)
36	24 340	Direct Blue 10	3,3'-Dimethoxybenzidine (o-Dianisidine)
37	23 850	Direct Blue 14	3,3'-Dimethylbenzidine (o-Tolidine)
38	24 400	Direct Blue 15	3,3'-Dimethoxybenzidine (o-Dianisidine)

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
39	23 710	Direct Blue 21	3,3'-Dimethylbenzidine (o-Tolidine)
40	24 280	Direct Blue 22	3,3'-Dimethoxybenzidine (o-Dianisidine)
41	23 790	Direct Blue 25	3,3'-Dimethylbenzidine (o-Tolidine)
42	24 145	Direct Blue 35	3,3'-Dimethoxybenzidine (o-Dianisidine)
43	24 175	Direct Blue 151	3,3'-Dimethoxybenzidine (o-Dianisidine)
44	-	Direct Blue 160	3,3'-Dimethoxybenzidine (o-Dianisidine)
45	-	Direct Blue 173	3,3'-Dimethoxybenzidine (o-Dianisidine)
46	-	Direct Blue 192	3,3'-Dimethoxybenzidine (o-Dianisidine)
47	-	Direct Blue 201	3,3'-Dimethoxybenzidine (o-Dianisidine)
48	24 415	Direct Blue 215	3,3'-Dimethoxybenzidine (o-Dianisidine)
49	23 820	Direct Blue 295	3,3'-Dimethylbenzidine (o-Tolidine)
50	24 203	Direct Blue 306	3,3'-Dimethoxybenzidine (o-Dianisidine)
51	30 045	Direct Brown 1	Benzidine
52	30 110	Direct Brown 1:2	Benzidine
53	22 311	Direct Brown 2	Benzidine
54	30 140	Direct Brown 6	Benzidine
55	36 030	Direct Brown 25	Benzidine
56	31 725	Direct Brown 27	Benzidine
57	35 660	Direct Brown 31	Benzidine
58	35 520	Direct Brown 33	Benzidine
59	31 710	Direct Brown 51	Benzidine
60	22 345	Direct Brown 59	Benzidine
61	36 300	Direct Brown 74	Benzidine
62	30 050	Direct Brown 79	Benzidine
63	30 145	Direct Brown 95	Benzidine
64	31 740	Direct Brown 101	Benzidine
65	30 120	Direct Brown 154	Benzidine
66	30 368	Direct Brown 222	3,3'-Dimethylbenzidine (o-Tolidine)
67	-	Direct Brown 223	3,3'-Dimethylbenzidine (o-Tolidine)
68	21 060	Direct Dye	Benzidine
69	30 280	Direct Green 1	Benzidine
70	30 295	Direct Green 6	Benzidine
71	30 315	Direct Green 8	Benzidine
72	-	Direct Green 8:1	Benzidine
73	30 387	Direct Green 85	3,3'-Dimethylbenzidine (o-Tolidine)
74	22 370	Direct Orange 1	Benzidine
75	23 375	Direct Orange 6, Dinatriumsalz	3,3'-Dimethylbenzidine (o-Tolidine)
76	23 380	Direct Orange 7	3,3'-Dimethylbenzidine (o-Tolidine)
77	22 130	Direct Orange 8	Benzidine
78	23 370	Direct Orange 10	3,3'-Dimethylbenzidine (o-Tolidine)
79	29 173	Direct Orange 108	o-Toluidine
80	22 310	Direct Red 1	Benzidine
81	23 500	Direct Red 2	3,3'-Dimethylbenzidine (o-Tolidine)
82	24 100	Direct Red 7	3,3'-Dimethoxybenzidine (o-Dianisidine)
83	22 145	Direct Red 10	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
84	22 155	Direct Red 13	Benzidine
85	22 150	Direct Red 17	Benzidine
86	23 560	Direct Red 21	3,3'-Dimethylbenzidine (o-Tolidine)
87	23 565	Direct Red 22	3,3'-Dimethylbenzidine (o-Tolidine)
88	22 120	Direct Red 28	Benzidine
89	22 240	Direct Red 37	Benzidine
90	23 630	Direct Red 39	3,3'-Dimethylbenzidine (o-Tolidine)
91	22 500	Direct Red 44	Benzidine
92	23 050	Direct Red 46	Dichlorobenzidine
93	29 175	Direct Red 62	o-Toluidine
94	23 505	Direct Red 67	3,3'-Dimethylbenzidine (o-Tolidine)
95	22 570	Direct Violet 1	Benzidine
96	22 555	Direct Violet 4	Benzidine
97	22 550	Direct Violet 12	Benzidine
98	24 080	Direct Violet 13	3,3'-Dimethoxybenzidine (o-Dianisidine)
99	23 520	Direct Violet 21	3,3'-Dimethylbenzidine (o-Tolidine)
100	22 480	Direct Violet 22	Benzidine
101	22 250	Direct Yellow 1	Benzidine
102	22 010	Direct Yellow 24	Benzidine
103	23 660	Direct Yellow 48	3,3'-Dimethylbenzidine (o-Tolidine)
104	-	Disperse Orange 60	Dichlorobenzidine
105	-	Disperse Red 221	p-Chloroaniline
106	-	Disperse Yellow 218	p-Chloroaniline
107	22 310	Mordant Red 57	Benzidine
108	-	Mordant Yellow 16	4,4'-Thiodianiline
109	-	Solvent Red 19 (ähnlich)	o-Toluidine
110	26 105	Solvent Red 24	o-Aminoazotoluene, o-Toluidine
111	26 120	Solvent Red 26	o-Toluidine
112	-	Solvent Red 164	o-Toluidine
113	-	Solvent Red 215	o-Aminoazotoluene, o-Toluidine

Annex 3

Table 2 : Azo dyes which are split into carcinogenic amines corresponding to the German Bedarfsgegenständeverordnung, not available on the world market

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
1	20 500	Acid Black 28	2-Amino-4-nitrotoluene
2	30 275	Acid Black 66	Benzidine
3	30 355	Acid Black 70	Benzidine / o-Toluidine
4	14 810	Acid Dye	o-Toluidine
5	15 000	Acid Dye	b-Naphthylamine
6	16 010	Acid Dye	o-Toluidine
7	19 610	Acid Dye	o-Toluidine
8	22 255	Acid Dye	Benzidine
9	22 285	Acid Dye	Benzidine
10	22 400	Acid Dye	Benzidine
11	23 070	Acid Dye	Dichlorobenzidine
12	25 110	Acid Dye	4,4'-Thiodianiline
13	25 115	Acid Dye	4,4'-Thiodianiline
14	16 011	Acid Orange 16	o-Toluidine
15	15 995	Acid Orange 31	p-Chloroaniline
16	24 765	Acid Orange 55	3,3'-Dimethyl-4,4'-diaminodiphenylmethane
17	14 920	Acid Red 16	b-Naphthylamine
18	14 940	Acid Red 22	p-Cresidine
19	-	Acid Red 25:1	
20	27 015	Acid Red 177	o-Aminoazotoluene, o-Toluidine
21	22 238	Acid Red 323	Benzidine
22	37 270	Azoic Diazo Component	b-Naphthylamine
23	37 077	Azoic Diazo Component / Azoic Brown 29	o-Toluidine
24	37 210	Azoic Diazo Component 4	o-Aminoazotoluene, o-Toluidine
25	37 080	Azoic Diazo Component 11	4-Chloro-o-toluidine
26	37 230	Azoic Diazo Component 113	3,3'-Dimethylbenzidine (o-Tolidine)
27	21 030	Basic Brown 2	2,4-Diaminoanisol
28	11 280	Basic Dye	o-Toluidine
29	30 240	Direct Black 11	Benzidine
30	30 345	Direct Black 14	Benzidine
31	22 620	Direct Black 15	Benzidine
32	30 395	Direct Black 20	3,3'-Dimethylbenzidine (o-Tolidine)
33	31 925	Direct Black 24	Benzidine
34	31 810	Direct Black 27	Benzidine
35	23 675	Direct Black 30	3,3'-Dimethylbenzidine (o-Tolidine)
36	35 075	Direct Black 34	Benzidine
37	31 760	Direct Black 40	Benzidine
38	30 260	Direct Black 41, Acid Black 69	Benzidine
39	31 850	Direct Black 83	Benzidine
40	24 115	Direct Black 86	3,3'-Dimethoxybenzidine (o-Dianisidine)

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
41	24 110	Direct Black 87	3,3'-Dimethoxybenzidine (o-Dianisidine)
42	35 415	Direct Black 100	Benzidine
43	-	Direct Black 126	Benzidine
44	30 270	Direct Black 131	Benzidine
45	24 380	Direct Blue 4	3,3'-Dimethoxybenzidine (o-Dianisidine)
46	30 350	Direct Blue 11	Benzidine
47	24 170	Direct Blue 12	3,3'-Dimethoxybenzidine (o-Dianisidine)
48	22 475	Direct Blue 16	Benzidine
49	22 485	Direct Blue 19	Benzidine
50	24 405	Direct Blue 23	3,3'-Dimethoxybenzidine (o-Dianisidine)
51	31 930	Direct Blue 26	Benzidine
52	23 750	Direct Blue 27	3,3'-Dimethylbenzidine (o-Tolidine)
53	31 955	Direct Blue 30	3,3'-Dimethoxybenzidine (o-Dianisidine)
54	23 690	Direct Blue 31	3,3'-Dimethylbenzidine (o-Tolidine)
55	24 150	Direct Blue 36	3,3'-Dimethoxybenzidine (o-Dianisidine)
56	24 270	Direct Blue 37	3,3'-Dimethoxybenzidine (o-Dianisidine)
57	30 090	Direct Blue 38	Benzidine
58	30 390	Direct Blue 39	3,3'-Dimethylbenzidine (o-Tolidine)
59	22 505	Direct Blue 42	Benzidine
60	30 205	Direct Blue 43	Benzidine
61	24 310	Direct Blue 45	3,3'-Dimethoxybenzidine (o-Dianisidine)
62	22 565	Direct Blue 48	Benzidine
63	22 540	Direct Blue 49	Benzidine
64	24 205	Direct Blue 50	3,3'-Dimethoxybenzidine (o-Dianisidine)
65	30 340	Direct Blue 51	Benzidine
66	23 860	Direct Blue 53	3,3'-Dimethylbenzidine (o-Tolidine)
67	22 490	Direct Blue 58	Benzidine
68	23 810	Direct Blue 60	3,3'-Dimethylbenzidine (o-Tolidine)
69	31 910	Direct Blue 63	Benzidine
70	22 595	Direct Blue 64	Benzidine
71	24 220	Direct Blue 65	3,3'-Dimethoxybenzidine (o-Dianisidine)
72	35 085	Direct Blue 131	Benzidine
73	24 065	Direct Blue 136	3,3'-Dimethoxybenzidine (o-Dianisidine)
74	33 560	Direct Blue 163	p-Cresidine
75	22 625	Direct Blue 177	Benzidine
76	31 951	Direct Blue 183	3,3'-Dimethoxybenzidine (o-Dianisidine)
77	22 455	Direct Blue 230	Benzidine
78	23 830	Direct Blue 231	3,3'-Dimethylbenzidine (o-Tolidine)
79	35 210	Direct Brown	Benzidine
80	30 135	Direct Brown 5	Benzidine
81	30 035	Direct Brown 7	Benzidine
82	35 710	Direct Brown 13	Benzidine
83	35 715	Direct Brown 14	Benzidine
84	30 100	Direct Brown 17	Benzidine
85	30 060	Direct Brown 20	Benzidine
86	30 155	Direct Brown 21	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
87	31 700	Direct Brown 24	Benzidine
88	31 730	Direct Brown 26	Benzidine
89	35 060	Direct Brown 39	Benzidine
90	35 700	Direct Brown 43	Benzidine
91	31 785	Direct Brown 46	Benzidine
92	31 885	Direct Brown 52	Benzidine
93	31 735	Direct Brown 54	Benzidine
94	22 040	Direct Brown 56	Benzidine
95	31 705	Direct Brown 57	Benzidine
96	22 340	Direct Brown 58	Benzidine
97	22 325	Direct Brown 60	Benzidine
98	30 055	Direct Brown 61	Benzidine
99	31 720	Direct Brown 62	Benzidine
100	30 125	Direct Brown 68	Benzidine
101	35 530	Direct Brown 70	Benzidine
102	35 535	Direct Brown 73	Benzidine
103	30 325	Direct Brown 75	Benzidine
104	22 030	Direct Brown 86	Benzidine
105	23 360	Direct Brown 147	Dichlorobenzidine
106	31 685	Direct Brown 151	Benzidine
107	30 070	Direct Brown 158	Benzidine
108	31 755	Direct Brown 159	Benzidine
109	30 040	Direct Brown 171	Benzidine
110	30 165	Direct Brown 173	Benzidine
111	30 150	Direct Brown 175	Benzidine
112	31 750	Direct Brown 190	Benzidine
113	35 720	Direct Brown 215	Benzidine
114	19 565	Direct Dye	o-Toluidine
115	22 000	Direct Dye	Benzidine
116	22 020	Direct Dye	Benzidine
117	22 035	Direct Dye	Benzidine
118	22 050	Direct Dye	Benzidine
119	22 060	Direct Dye	Benzidine
120	22 070	Direct Dye	Benzidine
121	22 080	Direct Dye	Benzidine
122	22 090	Direct Dye	Benzidine
123	22 095	Direct Dye	Benzidine
124	22 100	Direct Dye	Benzidine
125	22 110	Direct Dye	Benzidine
126	22 125	Direct Dye	Benzidine
127	22 140	Direct Dye	Benzidine
128	22 160	Direct Dye	Benzidine
129	22 165	Direct Dye	Benzidine
130	22 175	Direct Dye	Benzidine
131	22 210	Direct Dye	Benzidine
132	22 220	Direct Dye	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
133	22 230	Direct Dye	Benzidine
134	22 260	Direct Dye	Benzidine
135	22 300	Direct Dye	Benzidine
136	22 320	Direct Dye	Benzidine
137	22 330	Direct Dye	Benzidine
138	22 335	Direct Dye	Benzidine
139	22 390	Direct Dye	Benzidine
140	22 415	Direct Dye	Benzidine
141	22 495	Direct Dye	Benzidine
142	22 530	Direct Dye	Benzidine
143	22 545	Direct Dye	Benzidine
144	22 585	Direct Dye	Benzidine
145	22 600	Direct Dye	Benzidine
146	22 605	Direct Dye	Benzidine
147	23 045	Direct Dye	Dichlorobenzidine
148	23 350	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
149	23 385	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
150	23 390	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
151	23 400	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
152	23 530	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
153	23 540	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
154	23 550	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
155	23 580	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
156	23 585	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
157	23 590	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
158	23 595	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
159	23 610	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
160	23 620	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
161	23 625	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
162	23 645	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
163	23 650	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
164	23 695	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
165	23 700	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
166	23 715	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
167	23 720	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
168	23 730	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
169	23 740	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
170	23 745	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
171	23 760	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
172	23 770	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
173	23 780	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
174	23 785	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
175	23 795	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
176	23 825	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
177	23 835	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
178	23 840	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
179	24 050	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
180	24 060	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
181	24 070	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
182	24 075	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
183	24 090	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
184	24 120	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
185	24 160	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
186	24 165	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
187	24 180	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
188	24 190	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
189	24 195	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
190	24 200	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
191	24 210	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
192	24 215	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
193	24 225	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
194	24 230	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
195	24 240	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
196	24 250	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
197	24 260	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
198	24 290	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
199	24 300	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
200	24 320	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
201	24 325	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
202	24 330	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
203	24 335	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
204	24 345	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
205	24 350	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
206	24 355	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
207	24 361	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
208	24 365	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
209	24 375	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
210	24 385	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
211	24 390	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
212	24 395	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
213	24 420	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
214	26 725	Direct Dye	o-Toluidine
215	29 250	Direct Dye	o-Toluidine
216	29 255	Direct Dye	o-Toluidine
217	29 260	Direct Dye	b-Naphthylamine
218	30 065	Direct Dye	Benzidine
219	30 075	Direct Dye	Benzidine
220	30 080	Direct Dye	Benzidine
221	30 085	Direct Dye	Benzidine
222	30 095	Direct Dye	Benzidine
223	30 105	Direct Dye	Benzidine
224	30 130	Direct Dye	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
225	30 160	Direct Dye	Benzidine
226	30 170	Direct Dye	Benzidine
227	30 175	Direct Dye	Benzidine
228	30 180	Direct Dye	Benzidine
229	30 190	Direct Dye	Benzidine
230	30 195	Direct Dye	Benzidine
231	30 200	Direct Dye	Benzidine
232	30 210	Direct Dye	Benzidine
233	30 215	Direct Dye	Benzidine
234	30 230	Direct Dye	Benzidine
235	30 250	Direct Dye	Benzidine
236	30 265	Direct Dye	Benzidine
237	30 300	Direct Dye	Benzidine
238	30 320	Direct Dye	Benzidine
239	30 335	Direct Dye	Benzidine
240	30 360	Direct Dye	Benzidine
241	30 370	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
242	30 375	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
243	30 385	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
244	31 690	Direct Dye	Benzidine
245	31 695	Direct Dye	Benzidine
246	31 715	Direct Dye	Benzidine
247	31 745	Direct Dye	Benzidine
248	31 765	Direct Dye	Benzidine
249	31 770	Direct Dye	Benzidine
250	31 780	Direct Dye	Benzidine
251	31 793	Direct Dye	Benzidine
252	31 795	Direct Dye	Benzidine
253	31 800	Direct Dye	Benzidine
254	31 805	Direct Dye	Benzidine
255	31 815	Direct Dye	Benzidine
256	31 820	Direct Dye	Benzidine
257	31 825	Direct Dye	Benzidine
258	31 830	Direct Dye	Benzidine
259	31 835	Direct Dye	Benzidine
260	31 840	Direct Dye	Benzidine
261	31 845	Direct Dye	Benzidine
262	31 855	Direct Dye	Benzidine
263	31 875	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
264	31 880	Direct Dye	Benzidine
265	31 890	Direct Dye	Benzidine
266	31 895	Direct Dye	Benzidine
267	31 900	Direct Dye	Benzidine
268	31 905	Direct Dye	Benzidine
269	31 915	Direct Dye	Benzidine
270	31 920	Direct Dye	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
271	31 935	Direct Dye	Benzidine
272	31 940	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
273	31 945	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
274	31 950	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
275	31 960	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
276	31 965	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
277	31 970	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
278	33 350	Direct Dye	
279	35 065	Direct Dye	Benzidine
280	35 070	Direct Dye	Benzidine
281	35 080	Direct Dye	Benzidine
282	35 100	Direct Dye	Benzidine
283	35 220	Direct Dye	Benzidine
284	35 225	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
285	35 230	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
286	35 240	Direct Dye	Benzidine
287	35 400	Direct Dye	Benzidine
288	35 540	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
289	35 650	Direct Dye	Benzidine
290	35 670	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
291	35 680	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
292	35 730	Direct Dye	3,3'-Dimethoxybenzidine (o-Dianisidine)
293	35 900	Direct Dye	Benzidine
294	36 040	Direct Dye	Benzidine
295	36 210	Direct Dye	Benzidine
296	36 220	Direct Dye	3,3'-Dimethylbenzidine (o-Tolidine)
297	30 330	Direct Green 7	Benzidine
298	30 310	Direct Green 9	Benzidine
299	30 285	Direct Green 10	Benzidine
300	30 290	Direct Green 12	Benzidine
301	30 305	Direct Green 19	Benzidine
302	30 380	Direct Green 20	3,3'-Dimethylbenzidine (o-Tolidine)
303	31 790	Direct Green 21	Benzidine
304	22 322	Direct Green 21:1	Benzidine
305	31 775	Direct Green 22	Benzidine
306	30 220	Direct Green 39	Benzidine
307	24 130	Direct Green 57	3,3'-Dimethoxybenzidine (o-Dianisidine)
308	30 225	Direct Green 58	Benzidine
309	22 315	Direct Green 60	Benzidine
310	22 375	Direct Orange 1	Benzidine
311	22 380	Direct Orange 2	Benzidine
312	23 605	Direct Orange 13	3,3'-Dimethylbenzidine (o-Tolidine)
313	22 135	Direct Orange 25	Benzidine
314	23 665	Direct Orange 30, Dinatriumsalz	3,3'-Dimethylbenzidine (o-Tolidine)
315	23 655	Direct Orange 31	3,3'-Dimethylbenzidine (o-Tolidine)
316	22 385	Direct Orange 33	Benzidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
317	22 190	Direct Orange 101	Benzidine
318	19 590	Direct Red 119	o-Toluidine
319	19 500	Direct Red 142	o-Toluidine
320	23 510	Direct Red 15	3,3'-Dimethylbenzidine (o-Tolidine)
321	22 280	Direct Red 18	Benzidine
322	22 305	Direct Red 29	Benzidine
323	22 306	Direct Red 33	Benzidine
324	23 570	Direct Red 34	3,3'-Dimethylbenzidine (o-Tolidine)
325	22 180	Direct Red 42	Benzidine
326	22 205	Direct Red 43	Benzidine
327	22 290	Direct Red 52	Benzidine
328	22 405	Direct Red 53	Benzidine
329	23 600	Direct Red 56	3,3'-Dimethylbenzidine (o-Tolidine)
330	22 420	Direct Red 59	Benzidine
331	22 200	Direct Red 60	Benzidine
332	23 040	Direct Red 61	Dichlorobenzidine
333	17 870	Direct Red 65	o-Toluidine
334	23 515	Direct Red 68	3,3'-Dimethylbenzidine (o-Tolidine)
335	29 180	Direct Red 73	o-Toluidine
336	22 170	Direct Red 74	Benzidine
337	22 360	Direct Red 88	Benzidine
338	22 445	Direct Violet 3	Benzidine
339	27 660	Direct Violet 5	o-Toluidine
340	22 465	Direct Violet 17	Benzidine
341	22 460	Direct Violet 27	Benzidine
342	23 685	Direct Violet 28	3,3'-Dimethylbenzidine (o-Tolidine)
343	24 105	Direct Violet 32	3,3'-Dimethoxybenzidine (o-Dianisidine)
344	22 470	Direct Violet 36	Benzidine
345	24 370	Direct Violet 37	3,3'-Dimethoxybenzidine (o-Dianisidine)
346	22 630	Direct Violet 38	Benzidine
347	23 680	Direct Violet 39	3,3'-Dimethylbenzidine (o-Tolidine)
348	22 450	Direct Violet 42	Benzidine
349	22 440	Direct Violet 43	Benzidine
350	22 510	Direct Violet 45	Benzidine
351	22 520	Direct Violet 85	Benzidine
352	23 640	Direct Yellow 2	3,3'-Dimethylbenzidine (o-Tolidine)
353	22 410	Direct Yellow 20	Benzidine
354	37 235	Disperse Black 6	3,3'-Dimethoxybenzidine (o-Dianisidine)
355	12 476	Disperse Red 220	4-Chloro-o-toluidine
356	30 255	Leather Dye	Benzidine
357	14 085	Mordant Dye	Benzidine
358	22 270	Mordant Dye	Benzidine
359	22 275	Mordant Dye	Benzidine
360	14 135	Mordant Yellow	Benzidine
361	25 100	Mordant Yellow 16	4,4'-Thiodianiline
362	12 100	Solvent Orange 2	o-Toluidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
363	12 175	Solvent Orange 8	b-Naphthylamine
364	26 075	Solvent Orange 13	o-Aminoazotoluene, o-Toluidine
365	12 005	Solvent Red 2	o-Toluidine
366	26 766	Solvent Red 32	o-Aminoazotoluene, o-Toluidine
367	11 160	Solvent Yellow 3	o-Aminoazotoluene, o-Toluidine
368	11 390	Solvent Yellow 6	o-Toluidine
369	11 860	Solvent Yellow 12	o-Toluidine
370	21 140	Solvent Yellow 107	Dimethylbenzidine (o-Tolidine)

Annex 3

Table 3 : Azo dyes which are split into carcinogenic amines not included in the German Bedarfsgegenständeverordnung, available on the world market

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
1	-	Acid Black 131	o-Anisidine
2	-	Acid Black 132	o-Anisidine
3	-	Acid Brown 415	o-Anisidine
4	14 710	Acid Red 4	o-Anisidine
5	14 905	Acid Red 5	o-Anisidine
6	27 290	Acid Red 73	p-Aminoazobenzene
7	26 660	Acid Red 116	p-Aminoazobenzene
8	27 190	Acid Red 150	p-Aminoazobenzene
9	18 133	Acid Red 264	o-Anisidine
10	-	Acid Red 420	p-Aminoazobenzene
11	18 075	Acid Violet 12	o-Anisidine
12	-	Basic Red 42	o-Anisidine
13	12 245	Basic Red 76	o-Anisidine
14	-	Basic Red 111	p-Aminoazobenzene
15	-	Basic Red 114	o-Anisidine
16	-	Basic Yellow 82	p-Aminoazobenzene
17	29 185	Direct Red 24	o-Anisidine
18	29 190	Direct Red 26	o-Anisidine
19	29 200	Direct Red 72	o-Anisidine
20	-	Disperse Orange 149	p-Aminoazobenzene
21	26 130	Disperse Red 151	p-Aminoazobenzene
22	26 090	Disperse Yellow 7	p-Aminoazobenzene
23	26 070	Disperse Yellow 23	p-Aminoazobenzene
24	-	Disperse Yellow 56	p-Aminoazobenzene
25	12 150	Solvent Red 1	o-Anisidine
26	26 050	Solvent Red 19	p-Aminoazobenzene
27	26 100	Solvent Red 23	p-Aminoazobenzene
28	-	Solvent Red 68	p-Aminoazobenzene
29	27 290	Solvent Red 69	p-Aminoazobenzene
30	-	Solvent Yellow 72	o-Anisidine

Annex 3

Table 4 : Azo dyes which are split into carcinogenic amines not included in the German Bedarfsgegenständeverordnung, not available on the world market

Nr.	*C.I.-Nr.*	*Name / Synonym*	*Diazokomponente*
1	17 570	Acid Brown 89	o-Anisidine
2	33 545	Acid Green 33	p-Aminoazobenzene
3	18 025	Acid Red 107	o-Anisidine
4	26 207	Acid Red 350	p-Aminoazobenzene
5	37 115	Azoic Diazo Component	o-Anisidine
6	29 205	Direct Dye	o-Anisidine
7	29 170	Direct Red 14	o-Anisidine
8	27 780	Direct Red 55	o-Anisidine
9	17 875	Direct Red 64	o-Anisidine
10	17 820	Direct Red 123	o-Anisidine
11	26 020	Solvent Orange 14	p-Aminoazobenzene
12	27 306	Solvent Red 31	p-Aminoazobenzene
13	27 305	Solvent Red 110	p-Aminoazobenzene
14	11 000	Solvent Yellow 1	p-Aminoazobenzene
15	14 070	Solvent Yellow 20	o-Anisidine

Annex 3

Table 5 : Azo dyes which are split into the carcinogenic amines 2,4-xylidine or 2,6-xylidine

No.	*C.I.-No.*	*Name / Synonym*	*Diazocomponent*
1	20170	Acid Orange 24	2,4-xylidine and 2,6-xylidine
2	26125	Solvent Red 27	2,4-xylidine and 2,6-xylidine
3	16020	Acid Orange 17	2,4-xylidine
4	20170	Acid Orange 24	2,4-xylidine
5	14900	Acid Red 8	2,4-xylidine
6	16150	Acid Red 26	2,4-xylidine
7	16151	Acid Red 26:1	2,4-xylidine
8	16152	Acid Red 26:2	2,4-xylidine
9	18070	Acid Red 48	2,4-xylidine
10	14695	Acid Red 135	2,4-xylidine
11	27210	Acid Red 170	2,4-xylidine
12	17785	Direct Red 126	2,4-xylidine
13	19575	Direct Red 168	2,4-xylidine
14	17815	Direct Red 216	2,4-xylidine
15	29187	Direct Red 264	2,4-xylidine
16	29105	Direct Violet 14	2,4-xylidine
17	27980	Direct Blue 116	2,4-xylidine
18	12740	Solvent Yellow 16	2,4-xylidine
19	12140	Solvent Orange 7	2,4-xylidine
20	20020	Solvent Orange 30	2,4-xylidine