

## DIRECTIVES

## COMMISSION DIRECTIVE 2008/88/EC

of 23 September 2008

## amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products <sup>(1)</sup>, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, replaced by the Scientific Committee on Consumer Products (SCCP), by Commission Decision 2004/210/EC <sup>(2)</sup>, concluded that the potential risks were of concern. It recommended that the Commission take further steps to control the use of hair dye substances.
- (2) The Scientific Committee on Consumer Products further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity/mutagenicity.
- (3) Following the opinions of the SCCP, the Commission, together with Member States and stakeholders, agreed on an overall strategy to regulate substances used in hair dye products, according to which the industry was required to submit files containing the scientific data on hair dye substances to be evaluated by the SCCP.
- (4) Substances for which no updated safety files are submitted allowing an adequate risk assessment should be included in Annex II to Directive 76/768/EEC.
- (5) Some hair dye substances have already been banned, either as a result of opinions by the SCCP or due to

lack of safety data. The substances currently under consideration were carefully selected to be regulated together since they are listed in Annex IV. As no safety files on these substances for their use in hair dye products were submitted to the SCCP for a risk assessment by the agreed deadlines, there is no evidence that these substances, when used in hair dye products, can be considered safe for human health.

- (6) Substances without safety files 1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) and its dihydrochloride salt; 1,4-Dihydroxybenzene (Hydroquinone); [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammoniumchloride (Basic Blue 26); Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulpho-nate (Ponceau SX) and 4-[[4-Aminophenyl](4-aminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine and its hydrochloride salt (Basic Violet 14), currently listed as colorants in Annex IV and as hair dye substances in Annex III, Part 1 and Part 2, shall be deleted from Annex III and banned for use in hair dye products in Annex II.
- (7) Directive 76/768/EEC should therefore be amended accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annexes II and III to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

*Article 2*

1. Member States shall adopt and publish, by 14 February 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

<sup>(1)</sup> OJ L 262, 27.9.1976, p. 169.

<sup>(2)</sup> OJ L 66, 4.3.2004, p. 45.

They shall apply those provisions from 14 August 2009.

When Member States adopt those provisions, they 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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 23 September 2008.

*For the Commission*  
Günter VERHEUGEN  
*Vice-President*

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## ANNEX

Directive 76/768/EEC is amended as follows:

1. in Annex II, the following reference numbers 1329 to 1369 are added:

| Reference No | Chemical name/INCI-name  |
|--------------|--|
| 1329         | 4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine (CAS 3248-93-9; EINECS 221-832-2) and its hydrochloride salt (Basic Violet 14; CI 42510) (CAS 632-99-5; EINECS 211-189-6) when used as a substance in hair dye products   |
| 1330         | 4-(2,4-Dihydroxyphenylazo)benzenesulphonic acid (CAS 2050-34-2; EINECS 218-087-0) and its sodium salt (Acid Orange 6; CI 14270) (CAS 547-57-9; EINECS 208-924-8) when used as a substance in hair dye products   |
| 1331         | 3-Hydroxy-4-(phenylazo)-2-naphthoic acid (CAS 27757-79-5; EINECS 248-638-0) and its calcium salt (Pigment Red 64:1; CI 15800) (CAS 6371-76-2; EINECS 228-899-7), when used as a substance in hair dye products   |
| 1332         | 2-(6-Hydroxy-3-oxo-(3H)-xanthen-9-yl)benzoic acid; Fluorescein (CAS 2321-07-5; EINECS 219-031-8) and its disodium salt (Acid yellow 73 sodium salt; CI 45350) (CAS 518-47-8; EINECS 208-253-0), when used as a substance in hair dye products  |
| 1333         | 4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; 4',5'-Dibromofluorescein; (Solvent Red 72) (CAS 596-03-2; EINECS 209-876-0) and its disodium salt (CI 45370) (CAS 4372-02-5; EINECS 224-468-2) when used as a substance in hair dye products  |
| 1334         | 2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo-; (Solvent Red 43) (CAS 15086-94-9; EINECS 239-138-3), its disodium salt (Acid Red 87; CI 45380) (CAS 17372-87-1; EINECS 241-409-6) and its aluminium salt (Pigment Red 90:1 Aluminium lake) (CAS 15876-39-8; EINECS 240-005-7) when used as a substance in hair dye products |
| 1335         | Xanthylium, 9-(2-carboxyphenyl)-3-(2-methylphenyl)amino)-6-((2-methyl-4-sulfophenyl)amino)-, inner salt (CAS 10213-95-3); and its sodium salt (Acid Violet 9; CI 45190) (CAS 6252-76-2; EINECS 228-377-9) when used as a substance in hair dye products  |
| 1336         | 3',6'-Dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H]xanthene)-3-one; (Solvent Red 73) (CAS 38577-97-8; EINECS 254-010-7) and its sodium salt (Acid Red 95; CI 45425) (CAS 33239-19-9; EINECS 251-419-2) when used as a substance in hair dye products   |
| 1337         | 2',4',5',7'-Tetraiodofluorescein (CAS 15905-32-5; EINECS 240-046-0), its disodium salt (Acid Red 51; CI 45430) (CAS 16423-68-0; EINECS 240-474-8) and its aluminium salt (Pigment Red 172 Aluminium lake)(CAS 12227-78-0; EINECS 235-440-4) when used as a substance in hair dye products  |
| 1338         | 1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) (CAS 95-86-3; EINECS 202-459-4) and its dihydrochloride salt (2,4-Diaminophenol HCl) (CAS 137-09-7; EINECS 205-279-4) when used as a substance in hair dye products   |
| 1339         | 1,4-Dihydroxybenzene (Hydroquinone) (CAS 123-31-9; EINECS 204-617-8) when used as a substance in hair dye products   |
| 1340         | [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Blue 26; CI 44045) (CAS 2580-56-5; EINECS 219-943-6) when used as a substance in hair dye products  |
| 1341         | Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (Ponceau SX; CI 14700) (CAS 4548-53-2; EINECS 224-909-9) when used as a substance in hair dye products   |

| Reference No | Chemical name/INCI-name   |
|--------------|---|
| 1342         | Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)<br>(Acid Green 1; CI 10020) (CAS 19381-50-1; EINECS 243-010-2) when used as a substance in hair dye products  |
| 1343         | 4-(Phenylazo)resorcinol (Solvent Orange 1; CI 11920) (CAS 2051-85-6; EINECS 218-131-9) and its salts, when used as a substance in hair dye products   |
| 1344         | 4-[(4-Ethoxyphenyl)azo]naphthol (Solvent Red 3; CI 12010) (CAS 6535-42-8; EINECS 229-439-8) and its salts, when used as a substance in hair dye products  |
| 1345         | 1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) (CAS 2814-77-9; EINECS 220-562-2) and its salts when used as a substance in hair dye products  |
| 1346         | 3-Hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide (Pigment Red 112; CI 12370) (CAS 6535-46-2; EINECS 229-440-3) and its salts when used as a substance in hair dye products   |
| 1347         | N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxy-naphthalene-2-carboxamide (Pigment Red 5; CI 12490) (CAS 6410-41-9; EINECS 229-107-2) and its salts when used as a substance in hair dye products   |
| 1348         | Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (Pigment Red 48; CI 15865) (CAS 3564-21-4; EINECS 222-642-2) when used as a substance in hair dye products  |
| 1349         | Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate (Pigment Red 63; CI 15880) (CAS 6417-83-0; EINECS 229-142-3) when used as a substance in hair dye products  |
| 1350         | Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate (Acid Red 27; CI 16185) (CAS 915-67-3; EINECS 213-022-2) when used as a substance in hair dye products   |
| 1351         | 2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] (Pigment Yellow 13; CI 21100) (CAS 5102-83-0; EINECS 225-822-9) when used as a substance in hair dye products  |
| 1352         | 2,2'-[Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis[4-cyclohexylphenol] (Solvent Yellow 29; CI 21230) (CAS 6706-82-7; EINECS 229-754-0) when used as a substance in hair dye products   |
| 1353         | 1-((4-Phenylazo)phenylazo)-2-naphthol (Solvent Red 23; CI 26100) (CAS 85-86-9; EINECS 201-638-4) when used as a substance in hair dye products  |
| 1354         | Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate (Food Black 2; CI 27755) (CAS 2118-39-0; EINECS 218-326-9) when used as a substance in hair dye products   |
| 1355         | Ethanaminium, N-(4-((4-(diethylamino)phenyl)(2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, sodium salt (Acid Blue 1; CI 42045) (CAS 129-17-9; EINECS 204-934-1) when used as a substance in hair dye products  |
| 1356         | Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1) (Acid Blue 3; CI 42051) (CAS 3536-49-0; EINECS 222-573-8) when used as a substance in hair dye products                                |
| 1357         | Benzenemethanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfophenyl)methyl)amino)phenyl)(4-hydroxy-2-sulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt (Fast Green FCF; CI 42053) (CAS 2353-45-9; EINECS 219-091-5) when used as a substance in hair dye products |

| Reference No | Chemical name/INCI-name   |
|--------------|---|
| 1358         | 1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline (Solvent Yellow 33; CI 47000) (CAS 8003-22-3; EINECS 232-318-2) when used as a substance in hair dye products                |
| 1359         | Nigrosine (CI 50420) (CAS 8005-03-6) when used as a substance in hair dye products  |
| 1360         | 8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine (Pigment Violet 23; CI 51319) (CAS 6358-30-1; EINECS 228-767-9) when used as a substance in hair dye products             |
| 1361         | 1,2-Dihydroxyanthraquinone (Pigment Red 83; CI 58000) (CAS 72-48-0; EINECS 200-782-5) when used as a substance in hair dye products   |
| 1362         | Trisodium 8-hydroxypyrene-1,3,6-trisulphonate (Solvent Green 7; CI 59040) (CAS 6358-69-6; EINECS 228-783-6) when used as a substance in hair dye products   |
| 1363         | 1-Hydroxy-4-(p-toluidino)anthraquinone (Solvent Violet 13; CI 60725) (CAS 81-48-1; EINECS 201-353-5), when used as a substance in hair dye products   |
| 1364         | 1,4-bis(p-Tolylamino)anthraquinone (Solvent Green 3; CI 61565) (CAS 128-80-3; EINECS 204-909-5) when used as a substance in hair dye products   |
| 1365         | 6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one (VAT Red 1; CI 73360) (CAS 2379-74-0; EINECS 219-163-6) when used as a substance in hair dye products |
| 1366         | 5,12-Dihydroquino[2,3-b]acridine-7,14-dione (Pigment Violet 19; CI 73900) (CAS 1047-16-1; EINECS 213-879-2) when used as a substance in hair dye products   |
| 1367         | (29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32)copper (Pigment Blue 15; CI 74160) (CAS 147-14-8; EINECS 205-685-1) when used as a substance in hair dye products   |
| 1368         | Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32]cuprate(2-) (Direct Blue 86; CI 74180) (CAS 1330-38-7; EINECS 215-537-8) when used as a substance in hair dye products                   |
| 1369         | Polychloro copper phthalocyanine (Pigment Green 7; CI 74260) (CAS 1328-53-6; EINECS 215-524-7) when used as a substance in hair dye products'   |

2. Annex III is amended as follows:

- (a) in Part 1, reference number 10 is deleted;
- (b) in Part 1, column c of reference number 14, item (a) is deleted;
- (c) in Part 2, reference numbers 57, 59 and 60 are deleted.