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**Type:** Directive

**Concepts:** 1425, 2739, 2744, 4036, 5334, 5383

**Title:** Commission Directive 2007/54/EC of 29 August 2007 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 )

### **Recitals:**

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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 (1), 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 (2), 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.

(5) However 4,4'-Diaminodiphenylamine and its salts; 4-Diethylamino-o-toluidine and its salts; N,N-Diethyl-p-phenylenediamine and its salts; N,N-Dimethyl-p-phenylenediamine and its salts; and Toluene-3,4-Diamine and its salts, are currently listed under reference numbers 8 and 9 in Annex III, Part 1, which are general entries. Therefore they should be expressly deleted from general entries in Annex III. It is appropriate to list them in Annex II instead. Those annexes should therefore be amended accordingly.

(6) Directive 76/768/EEC should therefore be amended accordingly.

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

### **Main Body:**

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

1. Member States shall adopt and publish, by 18 March 2008 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.

They shall apply those provisions from 18 June 2008. 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.

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

This Directive is addressed to the Member States.

### **Attachments:**

Done at Brussels, 29 August 2007.

For the Commission

Günter VERHEUGEN

Vice-President

(1) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/22/EC (OJ L 101, 18.4.2007, p. 11).

(2) OJ L 66, 4.3.2004, p. 45.

#### **ANNEX**

Directive 76/768/EEC is amended as follows:

(1) In Annex II, the following reference numbers 1244 to 1328 are added:

Ref. No Chemical name/INCI-name

1244 1-Methyl-2,4,5-trihydroxybenzene (CAS No 1124-09-0) and its salts, when used as a substance in hair dye products

1245 2,6-Dihydroxy-4-methylpyridine (CAS No 4664-16-8) and its salts, when used as a substance in hair dye products

1246 5-Hydroxy-1,4-benzodioxane (CAS No 10288-36-5) and its salts, when used as a substance in hair dye products

1247 3,4-Methylenedioxyphenol (CAS No 533-31-3) and its salts, when used as a substance in hair dye products

1248 3,4-Methylenedioxyaniline (CAS No 14268-66-7) and its salts, when used as a substance in hair dye products

1249 Hydroxypyridinone (CAS No 822-89-9) and its salts, when used as a substance in hair dye products

1250 3-Nitro-4-aminophenoxyethanol (CAS No 50982-74-6) and its salts, when used as a substance in hair dye products

1251 2-methoxy-4-nitrophenol (CAS No 3251-56-7) (4-Nitroguaiacol) and its salts, when used as a substance in hair dye products

1252 C.I. Acid Black 131 (CAS No 12219-01-1) and its salts, when used as a substance in hair dye products

1253 1,3,5-Trihydroxybenzene (CAS No 108-73-6) (Phloroglucinol) and its salts, when used as a substance in hair dye products

1254 1,2,4-Benzenetriacetate (CAS No 613-03-6) and its salts, when used as a substance in hair dye products

1255 Ethanol, 2,2'-iminobis-, reaction products with epichlorohydrin and 2-nitro-1,4-benzenediamine (CAS No 68478-64-8) (CAS 158571-58-5) (HC Blue No 5) and its salts, when used as a substance in hair dye products

1256 N-Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and monoethanolamine (CAS No 158571-57-4) (HC Blue No 4) and its salts, when used as a substance in hair dye products

1257 4-Aminobenzenesulfonic acid (CAS No 121-57-3) and its salts, when used as a substance in hair dye products

1258 3,3'-(Sulfonylbis(2-nitro-4,1-phenylene)imino)bis(6-(phenylamino)) benzenesulfonic acid and its salts, when used as a substance in hair dye products

1259 3(or5)-((4-(Benzylmethylamino)phenyl)azo)-1,2-(or1,4)-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products

1260 2,2'-((3-Chloro-4-((2,6-dichloro-4-nitrophenyl)azo)phenyl)imino)bisethanol (CAS No 23355-64-8) (Disperse Brown 1) and its salts, when used as a substance in hair dye products

1261 Benzothiazolium, 2-[[4-[ethyl(2-hydroxyethyl)amino]phenyl]azo]-6-methoxy-3-methyl- and its salts, when used as a substance in hair dye products

1262 2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutanamide (CAS No 13515-40-7) (Pigment Yellow 73) and its salts, when used as a substance in hair dye products

1263 2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutanamide] (CAS No 6358-85-6) (Pigment Yellow 12) and its salts, when used as a substance in hair dye products

1264 2,2'-(1,2-Ethenediyl)bis[5-((4-ethoxyphenyl)azo)benzenesulfonic acid) and its salts, when used as a substance in hair dye products

1265 2,3-Dihydro-2,2-dimethyl-6-[(4-(phenylazo)-1-naphthalenyl)azo]-1H-pyrimidine (CAS No 4197-25-5) (Solvent Black 3) and its salts, when used as a substance in hair dye products

1266 3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1-naphthyl]azo]salicylic acid and its salts, when used as a substance in hair dye products

1267 2-Naphthalenesulfonic acid, 7-(benzoylamino)-4-hydroxy-3-[[4-[(4-sulfophenyl)azo]phenyl]azo]- and its salts, when used as a substance in hair dye products

1268 (μ-((7,7'-Iminobis(4-hydroxy-3-((2-hydroxy-5-(N-methylsulphamoyl)phenyl)azo)naphthalene-2-sulphonato))(6-)))dicuprate(2-) and its salts, when used as a substance in hair dye products

1269 3-[(4-(Acetylamino)phenyl)azo]-4-hydroxy-7-[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-2-naphthalenesulfonic acid and its salts, when used as a substance in hair dye products

1270 2-Naphthalenesulfonic acid, 7,7'-(carbonyldiimino)bis(4-hydroxy-3-[[2-sulfo-4-[(4-sulfophenyl)azo]phenyl]azo]-, (CAS No 25188-41-4) and its salts, when used as a substance in hair dye products

1271 Ethanaminium, N-(4-[bis[4-(diethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl- and its salts, when used as a substance in hair dye products

1272 3H-Indolium, 2-[[[4-methoxyphenyl)methyl]hydrazono]methyl]-1,3,3-trimethyl- and its salts, when used as a substance in hair dye products

1273 3H-Indolium, 2-(2-((2,4-dimethoxyphenyl)amino)ethenyl)-1,3,3-trimethyl- and its salts, when used as a substance in hair dye products

1274 Nigrosine spirit soluble (CAS No 11099-03-9) (Solvent Black 5), when used as a substance in

hair dye products

1275 Phenoxazin-5-ium, 3,7-bis(diethylamino)-, (CAS No 47367-75-9) and its salts, when used as a substance in hair dye products

1276 Benzo[a]phenoxazin-7-ium, 9-(dimethylamino)-, and its salts, when used as a substance in hair dye products

1277 6-Amino-2-(2,4-dimethylphenyl)-1H-benz[de]isoquinoline-1,3(2H)-dione (CAS No 2478-20-8) (Solvent Yellow 44) and its salts, when used as a substance in hair dye products

1278 1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone (CAS No 12217-43-5) and its salts, when used as a substance in hair dye products

1279 Laccaic Acid (CI Natural Red 25) (CAS No 60687-93-6) and its salts, when used as a substance in hair dye products

1280 Benzenesulfonic acid, 5-[(2,4-dinitrophenyl)amino]-2-(phenylamino)-, (CAS No 15347-52-1) and its salts, when used as a substance in hair dye products

1281 4-[(4-Nitrophenyl)azo]aniline (CAS No 730-40-5) (Disperse Orange 3) and its salts, when used as a substance in hair dye products

1282 4-Nitro-m-phenylenediamine (CAS No 5131-58-8) and its salts, when used as a substance in hair dye products

1283 1-Amino-4-(methylamino)-9,10-anthracenedione (CAS No 1220-94-6) (Disperse Violet 4) and its salts, when used as a substance in hair dye products

1284 N-Methyl-3-nitro-p-phenylenediamine (CAS No 2973-21-9) and its salts, when used as a substance in hair dye products

1285 N1-(2-Hydroxyethyl)-4-nitro-o-phenylenediamine (CAS No 56932-44-6) (HC Yellow No 5) and its salts, when used as a substance in hair dye products

1286 N1-(Tris(hydroxymethyl))methyl-4-nitro-1,2-phenylenediamine (CAS No 56932-45-7) (HC Yellow No 3) and its salts, when used as a substance in hair dye products

1287 2-Nitro-N-hydroxyethyl-p-anisidine (CAS No 57524-53-5) and its salts, when used as a substance in hair dye products

1288 N,N'-Dimethyl-N-Hydroxyethyl-3-nitro-p-phenylenediamine (CAS No 10228-03-2) and its salts, when used as a substance in hair dye products

1289 3-(N-Methyl-N-(4-methylamino-3-nitrophenyl)amino)propane-1,2-diol (CAS No 93633-79-5) and its salts, when used as a substance in hair dye products

1290 4-Ethylamino-3-nitrobenzoic acid (CAS No 2788-74-1) (N-Ethyl-3-Nitro PABA) and its salts, when used as a substance in hair dye products

1291 (8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl)trimethylammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17), when used as a substance in hair dye products

1292 5-((4-(Dimethylamino)phenyl)azo)-1,4-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products

1293 m-Phenylenediamine, 4-(phenylazo)-, (CAS No 495-54-5) and its salts, when used as a substance in hair dye products

1294 1,3-Benzenediamine, 4-methyl-6-(phenylazo)- and its salts, when used as a substance in hair dye products

1295 2,7-Naphthalenedisulfonic acid, 5-(acetlamino)-4-hydroxy-3-((2-methylphenyl)azo)- and its salts, when used as a substance in hair dye products

1296 4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1,3-benzenediamine] (CAS No 4482-25-1) (Basic Brown 4) and its salts, when used as a substance in hair dye products

1297 Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-2-methylphenyl]azo]-N,N,N-trimethyl- and its salts, when used as a substance in hair dye products

1298 Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-N,N,N-trimethyl- and its salts, when used as a substance in hair dye products

1299 Ethanaminium,  
N-[4-[(4-(diethylamino)phenyl)phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products

1300 9,10-Anthracenedione, 1-[(2-hydroxyethyl)amino]-4-(methylamino)- (CAS No 86722-66-9) and its derivatives and salts, when used as a substance in hair dye products

1301 1,4-Diamino-2-methoxy-9,10-anthracenedione (CAS No 2872-48-2) (Disperse Red 11) and its salts, when used as a substance in hair dye products

1302 1,4-Dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone (CAS No 3179-90-6) (Disperse Blue 7) and its salts, when used as a substance in hair dye products

1303 1-[(3-Aminopropyl)amino]-4-(methylamino)anthraquinone and its salts, when used as a substance in hair dye products

1304 N-[6-[(2-Chloro-4-hydroxyphenyl)imino]-4-methoxy-3-oxo-1,4-cyclohexadien-1-yl]acetamide (CAS No 66612-11-1) (HC Yellow No 8) and its salts, when used as a substance in hair dye products

1305 [6-[[3-Chloro-4-(methylamino)phenyl]imino]-4-methyl-3-oxocyclohexa-1,4-dien-1-yl]urea (CAS No 56330-88-2) (HC Red No 9) and its salts, when used as a substance in hair dye products

1306 Phenothiazin-5-ium, 3,7-bis(dimethylamino)- and its salts, when used as a substance in hair dye products

1307 4,6-Bis(2-Hydroxyethoxy)-m-Phenylenediamine and its salts, when used as a substance in hair dye products

1308 5-Amino-2,6-Dimethoxy-3-Hydroxypyridine (CAS No 104333-03-1) and its salts, when used as a substance in hair dye products

1309 4,4'-Diaminodiphenylamine (CAS No 537-65-5) and its salts, when used as a substance in hair dye products

1310 4-Diethylamino-o-toluidine (CAS No 148-71-0) and its salts, when used as a substance in hair dye products

1311 N,N-Diethyl-p-phenylenediamine (CAS No 93-05-0) and its salts, when used as a substance in hair dye products

1312 N,N-Dimethyl-p-phenylenediamine (CAS No 99-98-9) and its salts, when used as a substance in hair dye products

1313 Toluene-3,4-Diamine (CAS No 496-72-0) and its salts, when used as a substance in hair dye products

1314 2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts, when used as a substance in hair dye products

1315 6-Amino-o-cresol (CAS No 17672-22-9) and its salts, when used as a substance in hair dye products

1316 Hydroxyethylaminomethyl-p-aminophenol (CAS No 110952-46-0) and its salts, when used as a substance in hair dye products

1317 2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts, when used as a substance in hair dye products

1318 2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts, when used as a substance in hair dye products

1319 2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts, when used as a substance in hair dye products

1320 Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts, when used as a

substance in hair dye products

1321 6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts, when used as a substance in hair dye products

1322 Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl- and its salts, when used as a substance in hair dye products

1323 3-Hydroxy-4-[(2-hydroxynaphthyl)azo]-7-nitronaphthalene-1-sulphonic acid (CAS No 16279-54-2) and its salts, when used as a substance in hair dye products

1324 3-[(2-nitro-4-(trifluoromethyl)phenyl)amino]propane-1,2-diol (CAS No 104333-00-8) (HC Yellow No 6) and its salts, when used as a substance in hair dye products

1325 2-[(4-chloro-2-nitrophenyl)amino]ethanol (CAS No 59320-13-7) (HC Yellow No 12) and its salts, when used as a substance in hair dye products

1326 3-[[4-[(2-Hydroxyethyl)Methylamino]-2-Nitrophenyl]Amino]-1,2-Propanediol (CAS No 173994-75-7) and its salts, when used as a substance in hair dye products

1327 3-[[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino]-1,2-Propanediol (CAS No 114087-41-1) and its salts, when used as a substance in hair dye products

1328 Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products'

(2) Annex III is amended as follows:

(a) Part 1 is amended as follows:

(i) in column b of reference number 8, the words 'p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine, with exception of those derivatives listed elsewhere in this Annex' are replaced by the following 'p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine, with the exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II'.

(ii) in column b of reference number 9, the words 'Methylphenylenediamines, their N-substituted derivatives and their salts with the exception of substance No 364 in Annex II' are replaced by the following 'Methylphenylenediamines, their N-substituted derivatives and their salts with the exception of substances under reference numbers 364, 1310 and 1313 in Annex II'.

(b) In Part 2, reference numbers 1, 2, 8, 13, 15, 30, 41, 43, 45, 46, 51, 52, 53, and 54 are deleted.