

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)

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 ⁽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,

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 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.

⁽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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 August 2007.

For the Commission
Günter VERHEUGEN
Vice-President

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

Ref. No	Chemical name/INCI-name
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-sulfofenyl)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-sulfofenyl)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)methylhydrazono]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	Laccic 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

Ref. No	Chemical name/INCI-name
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-(acetylamino)-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

Ref. No	Chemical name/INCI-name
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

Ref. No	Chemical name/INCI-name
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.
