

Commission Directive 2005/80/EC of 21 November 2005 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress (Text with EEA relevance)

COMMISSION DIRECTIVE 2005/80/EC

of 21 November 2005

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes 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 4b and Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) Directive 76/768/EEC, as amended by Directive 2003/15/EC of the European Parliament and of the Council<sup>(2)</sup>, prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1, 2 and 3, under Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>(3)</sup>, but allows the use of substances classified in category 3 pursuant to Directive 67/548/EEC subject to evaluation and approval by the Scientific Committee on Cosmetic products and Non-Food Products intended for consumers SCCNFP, replaced by the Scientific Committee on Consumer Products (SCCP) by Commission Decision 2004/210<sup>(4)</sup>.
- (2) Directive 67/548/EEC has been amended by Directive 2004/73/EC, and it is therefore necessary to adopt measures so as to bring Directive 76/768/EEC in line with the provisions of Directive 67/548/EEC.
- (3) In so far as some of the substances classified as CMR of category 1 and 2 under Annex I to Directive 67/548/EEC are not yet listed in Annex II to Directive 76/768/EEC, it is necessary to include them in that Annex. Substances classified as CMR of category 3 under Annex I to Directive 67/548/EEC should also be included in Annex II to Directive 76/768/EEC, except if they have been evaluated by the SCCP and found acceptable for use in cosmetic products.
- (4) Substances classified as CMR of category 1 and 2 listed in Annex III, Part 1 to Directive 76/768/EEC should be deleted, since these substances are now listed in Annex II to

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Directive 76/768/EEC and therefore must not form part of the composition of cosmetic products.

- (5) Commission Directive 2004/93/EC<sup>(5)</sup> provided for the insertion in Annex II to Directive 76/768/EEC of certain substances which were already listed there. That Annex should therefore be amended for the sake of clarity.
- (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 text set out in the Annex to this Directive.

*Article 2*

Member States shall take all necessary measures to ensure that from 22 August 2006 cosmetic products which fail to comply with this Directive are not placed on the market by Community manufacturers or by importers established within the Community.

Member States shall take all necessary measures to ensure that those products are not sold or disposed of to the final consumer after 22 November 2006.

*Article 3*

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 22 May 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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 4*

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

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 21 November 2005.

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

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## ANNEX

Annexes II and III to Directive 76/768/EEC are amended as follows:

1. Annex II is amended as follows:

- (a) the entries under reference numbers 615 and 616 are deleted;
- (b) the entry under reference number 687 is replaced by the following:  
687. dinitrotoluene, technical grade (Cas No 121-14-2);
- (c) the following reference numbers 1137 and 1211 are added:

| Ref. No | Chemical name  | CAS NoEC No |
|---------|--|-------------|
| 1137    | isobutyl nitrite   | 542-56-3    |
| 1138    | isoprene (stabilized)<br>(2-methyl-1,3-butadiene)  | 78-79-5     |
| 1139    | 1-bromopropane<br>n-propyl bromide   | 106-94-5    |
| 1140    | chloroprene<br>(stabilized)<br>(2-chlorobuta-1,3-diene)  | 126-99-8    |
| 1141    | 1,2,3-trichloropropane   | 96-18-4     |
| 1142    | ethylene glycol<br>dimethyl ether<br>(EGDME)   | 110-71-4    |
| 1143    | dinocap (ISO)  | 39300-45-3  |
| 1144    | diaminotoluene,<br>technical product<br>-mixture of [4-methyl- <i>m</i> -phenylene<br>diamine] <sup>a</sup> and [2-methyl- <i>m</i> -phenylene<br>diamine] <sup>b</sup><br>methyl-phenylenediamine | 25376-45-8  |
| 1145    | <i>p</i> -chlorobenzotrichloride   | 5216-25-1   |
| 1146    | diphenylether;<br>octabromo derivate   | 32536-52-0  |
| 1147    | 1,2-bis(2-methoxyethoxy)ethane   | 112-49-2    |

**a** for the individual ingredient see reference number 364 in Annex II.

**b** for the individual ingredient see reference number 413 in Annex II.’

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ANNEX

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|      | triethylene glycol dimethyl ether (TEGDME)  |                 |
| 1148 | tetrahydrothiopyran-3-carboxaldehyde  | 61571-06-0      |
| 1149 | 4,4'-bis(dimethylamino)benzophenone (Michler's ketone)  | 90-94-8         |
| 1150 | oxiranemethanol, 4-methylbenzene-sulfonate, (S)-  | 70987-78-9      |
| 1151 | 1,2-benzenedicarboxylic acid, dipentylester, branched and linear [1]  | 84777-06-0 [1]  |
|      | n-pentyl-isopentylphthalate [2]   | -[2]            |
|      | di-n-pentyl phthalate [3]   | 131-18-0 [3]    |
|      | diisopentylphthalate [4]  | 605-50-5 [4]    |
| 1152 | benzyl butyl phthalate (BBP)  | 85-68-7         |
| 1153 | 1,2-benzenedicarboxylic acid di-C 7-11, branched and linear alkylesters   | 68515-42-4      |
| 1154 | a mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate and trisodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-oxido-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4- | EC No 402-660-9 |

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|      |   |                 |
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|      | diénylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate   |                 |
| 1155 | (methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diyl)))-1,1'-dipyridinium dichloride dihydrochloride   | EC No 401-500-5 |
| 1156 | 2-[2-hydroxy-3-(2-chlorophenyl) carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)-2-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]fluoren-9-one | EC No 420-580-2 |
| 1157 | azafenidin  | 68049-83-2      |
| 1158 | 2,4,5-trimethylaniline [1]  | 137-17-7 [1]    |
|      | 2,4,5-trimethylaniline hydrochloride [2]  | 21436-97-5 [2]  |
| 1159 | 4,4'-thiodianiline and its salts  | 139-65-1        |
| 1160 | 4,4'-oxydianiline ( <i>p</i> -aminophenyl ether) and its salts  | 101-80-4        |
| 1161 | <i>N,N,N',N'</i> -tetramethyl-4,4'-methylendianiline  | 101-61-1        |
| 1162 | 6-methoxy- <i>m</i> -toluidine ( <i>p</i> -cresidine)   | 120-71-8        |

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|      |  |                 |
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| 1163 | 3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine   | 143860-04-2     |
| 1164 | a mixture of:<br>1,3,5-tris(3-aminomethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione<br>and a mixture of oligomers of 3,5-bis(3-aminomethylphenyl)-1-poly[3,5-bis(3-aminomethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione | EC No 421-550-1 |
| 1165 | 2-nitrotoluene   | 88-72-2         |
| 1166 | tributyl phosphate   | 126-73-8        |
| 1167 | naphthalene  | 91-20-3         |
| 1168 | nonylphenol [1]  | 25154-52-3 [1]  |
|      | 4-nonylphenol, branched [2]  | 84852-15-3 [2]  |
| 1169 | 1,1,2-trichloroethane  | 79-00-5         |
| 1170 | pentachloroethane  | 76-01-7         |
| 1171 | vinylidene chloride (1,1-dichloroethylene)   | 75-35-4         |
| 1172 | allyl chloride (3-chloropropene)   | 107-05-1        |
| 1173 | 1,4-dichlorobenzene ( <i>p</i> -dichlorobenzene)   | 106-46-7        |
| 1174 | bis(2-chloroethyl) ether   | 111-44-4        |
| 1175 | phenol   | 108-95-2        |
| 1176 | bisphenol A (4,4'-isopropylidenediphenol)  | 80-05-7         |
| 1177 | trioxymethylene (1,3,5-trioxan)  | 110-88-3        |
| 1178 | propargite (ISO)   | 2312-35-8       |

**a** for the individual ingredient see reference number 364 in Annex II.

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|      |   |                 |
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| 1179 | 1-chloro-4-nitrobenzene   | 100-00-5        |
| 1180 | molinate (ISO)  | 2212-67-1       |
| 1181 | fenpropimorph   | 67564-91-4      |
| 1182 | epoxiconazole   | 133855-98-8     |
| 1183 | methyl isocyanate   | 624-83-9        |
| 1184 | N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate   | 118612-00-3     |
| 1185 | O,O'-(ethenylmethylsilylene) di[(4-methylpentan-2-one) oxime]   | EC No 421-870-1 |
| 1186 | a 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chroman-2-yl)resorcinol-4-yl-tris(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chroman-2-yl)resorcinolbis(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)  | 140698-96-0     |
| 1187 | a mixture of: reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:2) and reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3) | EC No 417-980-4 |
| 1188 | malachite green hydrochloride [1]   | 569-64-2 [1]    |

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|      | malachite green oxalate [2]   | 18015-76-4 [2]  |
| 1189 | 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol   | 107534-96-3     |
| 1190 | 5-(3-butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino)propyl]-3-hydroxycyclohex-2-en-1-one  | 138164-12-2     |
| 1191 | trans-4-phenyl-L-proline  | 96314-26-0      |
| 1192 | bromoxynil heptanoate (ISO)   | 56634-95-8      |
| 1193 | a mixture of: 5-[[4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo]benzoic acid and 5-[[4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl)azo]benzoic acid | 163879-69-4     |
| 1194 | 2-{4-(2-ammoniopropylamino)-6-[4-hydroxy-3-(5-methyl-2-methoxy-4-sulfamoylphenylazo)-2-sulfonatonaphth-7-ylamino]-1,3,5-triazin-2-ylamino}-2-aminopropyl formate  | EC No 424-260-3 |
| 1195 | 5-nitro- <i>o</i> -toluidine [1]  | 99-55-8 [1]     |
|      | 5-nitro- <i>o</i> -toluidine hydrochloride [2]  | 51085-52-0 [2]  |
| 1196 | 1-(1-naphthylmethyl)quinolinium   | 65322-65-8      |

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| 1197 | (R)-5-bromo-3-(1-methyl-2-pyrrolidinyl methyl)-1H-indole                                     | 143322-57-0     |
| 1198 | pymetrozine (ISO)  | 123312-89-0     |
| 1199 | oxadiargyl (ISO)   | 39807-15-3      |
| 1200 | chlorotoluron (3-(3-chloro- <i>p</i> -tolyl)-1,1-dimethylurea)                               | 15545-48-9      |
| 1201 | N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl] acetamide                      | EC No 416-860-9 |
| 1202 | 1,3-bis(vinylsulfonylacamido)-propane  | 93629-90-4      |
| 1203 | <i>p</i> -phenetidine (4-ethoxyaniline)  | 156-43-4        |
| 1204 | <i>m</i> -phenylenediamine and its salts   | 108-45-2        |
| 1205 | residues (coal tar), creosote oil distn., if it contains > 0,005 % w/w benzo[a]pyrene        | 92061-93-3      |
| 1206 | creosote oil, acenaphthene fraction, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene   | 90640-84-9      |
| 1207 | creosote oil, if it contains > 0,005 % w/w benzo[a]pyrene                                    | 61789-28-4      |
| 1208 | creosote, if it contains > 0,005 % w/w benzo[a]pyrene  | 8001-58-9       |
| 1209 | creosote oil, high-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene | 70321-79-8      |
| 1210 | extract residues (coal), creosote oil acid, wash   | 122384-77-4     |

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|          |   |            |
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|          | oil extract residue, if it contains > 0,005 % w/w benzo[a]pyrene                            |            |
| 1211     | creosote oil, low-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene | 70321-80-1 |
| <b>a</b> | for the individual ingredient see reference number 364 in Annex II.                         |            |
| <b>b</b> | for the individual ingredient see reference number 413 in Annex II.'                        |            |

2. Annex III, part one, is amended as follows:

- (a) the entry under reference number 19 is deleted;
- (b) under reference number 1a, column b the words '*Boric acid, borates and tetraborates*' are replaced by '*Boric acid, borates and tetraborates with the exception of substance No in Annex II*';
- (c) under reference number 8, column b the words '*m-and p-Phenylenediamine, their N-substituted derivatives and their salts; N-substituted derivatives of o-Phenylenediamine (<sup>δ</sup>), with exception of those derivatives listed elsewhere in this Annex*' are replaced by '*p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine (<sup>δ</sup>), with exception of those derivatives listed elsewhere in this Annex*'.

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- (1) [OJ L 262, 27.9.1976, p. 169](#). Directive as last amended by Commission Directive 2005/52/EC ([OJ L 234, 10.9.2005, p. 9](#)).
- (2) [OJ L 66, 11.3.2003, p. 26](#).
- (3) [OJ 196, 16.8.1967, p. 1](#). Directive as last amended by Commission Directive 2004/73/EC ([OJ L 152, 30.4.2004, p. 1](#)).
- (4) [OJ L 66, 4.3.2004, p. 45](#).
- (5) [OJ L 300, 25.9.2004, p. 13](#).