

Commission Directive 2005/79/EC of 18 November 2005 amending
Directive 2002/72/EC relating to plastic materials and articles
intended to come into contact with food (Text with EEA relevance)

COMMISSION DIRECTIVE 2005/79/EC

of 18 November 2005

amending Directive 2002/72/EC relating to plastic materials
and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC⁽¹⁾, and in particular Article 5(2) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Commission Directive 2002/72/EC⁽²⁾ establishes a list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. On the basis of new information related to the risk assessment of such substances, certain monomers provisionally admitted at national level as well as new monomers should be included in the Community list of permitted substances in that Directive.
- (2) Directive 2002/72/EC also contains an incomplete list of additives which may be used in the manufacture of plastic materials and articles. That list should be amended so as to include other additives evaluated by the European Food Safety Authority (the Authority).
- (3) For certain substances, the restrictions already established at Community level should be amended on the basis of the new information available. In particular for epoxidised soybean oil (ESBO) the Authority recommended to decrease its specific migration limit (SML) for PVC gaskets containing that substance which are used to seal glass jars containing infant formulae and follow-on formulae or containing processed cereal-based foods and baby foods for infants and young children. In fact the Authority noted that the exposure of infants who regularly eat such foods may exceed the TDI. Therefore the SML for ESBO is decreased for these particular applications from 60 to 30 mg/kg of food or food simulant while it remains unchanged for all other applications.
- (4) A transitional period should be provided for in respect of PVC gaskets containing epoxidised soybean oil, used to seal glass jars, which are brought into contact with food before the 19 November 2006.

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- (5) Directive 2002/72/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III, V and VI of Directive 2002/72/EC are amended in accordance with Annexes I to IV to this Directive.

Article 2

PVC gaskets containing epoxidised soybean oil, with reference number 88640 in section A of Annex III to Directive 2002/72/EC, which are used to seal glass jars containing infant formulae and follow-on formulae as defined by Commission Directive 91/321/EEC⁽³⁾ or containing processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 96/5/EC⁽⁴⁾, filled before 19 November 2006 and which comply with the restrictions and/or specifications provided for in Section A of Annex III to Directive 2002/72/EC as amended by Directive 2004/19/EC, may continue to be placed on the market provided that the date of filling appears on the materials and articles.

The date of filling may be replaced by another indication, provided that that indication permits the identification of the date of filling. Upon request the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Directive.

The first and second subparagraphs shall apply without prejudice to Directive 2000/13/EC of the European Parliament and of the Council⁽⁵⁾.

Article 3

1 Member States shall adopt and publish, by 19 November 2006 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 in such a way as to:

- a permit the trade in and use of plastic materials and articles intended to come into contact with food and complying with this Directive, from 19 November 2006;
- b prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with this Directive, from 19 November 2007.

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 20th 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, 18 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

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ANNEX I

Annex II to Directive 2002/72/EC is amended as follows:

1. point 2 of the general introduction is replaced by the following:
 2. The following substances are not included even if they are intentionally used and are authorised:
 - (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing "... acid(s), salts" appear in the lists, if the corresponding free acid(s) is (are) not mentioned;
 - (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:
 - (i) substances whose name contains "... acid(s), salts" which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,
 - (ii) substances referred to in note 38 of Annex VI.;
2. section A is amended as follows:
 - (a) the following lines are inserted in the table in numerical order:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|--|---|
| (1) | (2) | (3) | (4) |
| 11005 | 012542-30-2 | Acrylic acid, dicyclopentenyl ester | QMA = 0,05 mg/6 dm ² |
| 11500 | 000103-11-7 | Acrylic acid, 2-ethylhexyl ester | SML = 0,05 mg/kg |
| 12786 | 000919-30-2 | 3-Aminopropyltriethoxysilane | Residual oxidable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler. To be used only for the reactive surface treatment of inorganic fillers |
| 13317 | 132459-54-2 | N,N'-Bis[4-(ethoxycarbonyl)phenyl]1,5,8-naphthalenetetracarboxylic diimide | SML = 0,05 mg/kg filler (dew). To be used only as co-monomer (max 4 %) for |

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| | | | |
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| | | | polyesters (PET, PBT) |
| 14260 | 000502-44-3 | Caprolactone | SML = 0,05 mg/kg (expressed as the sum of caprolactone and 6-hydroxyhexanoic acid) |
| 16955 | 000096-49-1 | Ethylene carbonate | Residual content = 5 mg/kg of hydrogel at a maximum ratio of 10 g of hydrogel to 1 kg of food. The hydrolysate contains ethyleneglycol having an SML = 30 mg/kg |
| 21370 | 010595-80-9 | Methacrylic acid, 2-sulphoethyl ester | QMA = ND (DL = 0,02 mg/6 dm ²) |
| 22210 | 000098-83-9 | alpha-Methylstyrene | SML = 0,05 mg/kg |
| 22932 | 001187-93-5 | Perfluoromethyl perfluorovinyl ether | SML = 0,05 mg/kg. Only to be used for anti-stick coatings |
| 24903 | 068425-17-2 | Syrups, hydrolysed starch, hydrogenated | In compliance with the specifications laid down in Annex V |
| 25540 | 000528-44-9 | Trimellitic acid | SML(T) = 5 mg/kg ⁽³⁵⁾ |
| 25550 | 000552-30-7 | Trimellitic anhydride | SML(T) = 5 mg/kg ⁽³⁵⁾ (expressed as trimellitic acid) |

- (b) in the following lines the content of the columns 'CAS No' or 'Restrictions and/or specifications' is replaced by the following:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|--------|------|------------------------------------|
|--------------|--------|------|------------------------------------|

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| (1) | (2) | (3) | (4) |
|-------|-------------|---|----------------------------------|
| 10690 | 000079-10-7 | Acrylic acid | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 10750 | 002495-35-4 | Acrylic acid, benzyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 10780 | 000141-32-2 | Acrylic acid, n-butyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 10810 | 002998-08-5 | Acrylic acid, sec-butyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 10840 | 001663-39-4 | Acrylic acid, tert-butyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11470 | 000140-88-5 | Acrylic acid, ethyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11590 | 000106-63-8 | Acrylic acid, isobutyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11680 | 000689-12-3 | Acrylic acid, isopropyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11710 | 000096-33-3 | Acrylic acid, methyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11830 | 000818-61-1 | Acrylic acid, monoester with ethyleneglycol | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11890 | 002499-59-4 | Acrylic acid, n-octyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 11980 | 000925-60-0 | Acrylic acid, propyl ester | SML(T) = 6 mg/kg ⁽³⁶⁾ |
| 13720 | 000110-63-4 | 1,4-Butanediol | SML(T) = 5 mg/kg ⁽²⁴⁾ |
| 20020 | 000079-41-4 | Methacrylic acid | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 20080 | 002495-37-6 | Methacrylic acid, benzyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 20110 | 000097-88-1 | Methacrylic acid, butyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 20140 | 002998-18-7 | Methacrylic acid, sec-butyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |

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| 20170 | 000585-07-9 | Methacrylic acid, tert-butyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 20890 | 000097-63-2 | Methacrylic acid, ethyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21010 | 000097-86-9 | Methacrylic acid, isobutyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21100 | 004655-34-9 | Methacrylic acid, isopropyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21130 | 000080-62-6 | Methacrylic acid, methyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21190 | 000868-77-9 | Methacrylic acid, monoester with ethyleneglycol | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21280 | 002177-70-0 | Methacrylic acid, phenyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21340 | 002210-28-8 | Methacrylic acid, propyl ester | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 21460 | 000760-93-0 | Methacrylic anhydride | SML(T) = 6 mg/kg ⁽³⁷⁾ |
| 24190 | 008050-09-7 | Rosin wood | See “Rosin” (Reference No 24100)’ |

(c) the following line is deleted:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|--|------------------------------------|
| (1) | (2) | (3) | (4) |
| ‘11000 | 050976-02-8 | Acrylic acid, dicyclopentadienyl ester | QMA = 0,05 mg/6 dm ² ’ |

3. in section B the following lines are deleted:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|--------|------|------------------------------------|
| (1) | (2) | (3) | (4) |

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| ‘11500 | 000103-11-7 | Acrylic acid, 2-ethylhexyl ester | |
| 14260 | 000502-44-3 | Caprolactone | |
| 21370 | 010595-80-9 | Methacrylic acid, 2-sulphoethyl ester | |
| 22210 | 000098-83-9 | alpha-Methylstyrene | |
| 25540 | 000528-44-9 | Trimellitic acid | QM(T) = 5 mg/kg in FP |
| 25550 | 000552-30-7 | Trimellitic anhydride | QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)’ |

ANNEX II

Annex III to Directive 2002/72/EC is amended as follows:

1. point 2 is replaced by the following:
 2. The following substances are not included even if they are intentionally used and are authorised:
 - (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing “... acid(s), salts” appear in the lists, if the corresponding free acid(s) is (are) not mentioned;
 - (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:
 - (i) substances whose name contains “... acid(s), salts” which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,
 - (ii) substances referred to in note 38 of Annex VI.;
2. section A is amended as follows:
 - (a) the following lines are inserted in numerical order:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|--|------------------------------------|
| (1) | (2) | (3) | (4) |
| ‘30340 | 330198-91-9 | 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester | |

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| 30401 | — | Acetylated mono- and diglycerides of fatty acids | |
| 31542 | 174254-23-0 | Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters | QM = 0,5 % (w/w) in FP |
| 43480 | 064365-11-3 | Charcoal, activated | In compliance with the specifications laid down in Annex V, Part B |
| 62245 | 012751-22-3 | Iron phosphide | For PET polymers and copolymers only |
| 64990 | 025736-61-2 | Maleic anhydride-styrene, copolymer, sodium salt | In compliance with specifications laid down in Annex V |
| 66905 | 000872-50-4 | N-Methylpyrrolidone | |
| 66930 | 068554-70-1 | Methylsilsesquioxane | Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane |
| 67155 | — | Mixture of 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxazolyl)stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene | Not more than 0,05 % w/w (quantity of substance used/quantity of the formulation). In compliance with the specifications laid down in Annex V |
| 76415 | 019455-79-9 | Pimelic acid, calcium salt | |
| 76815 | — | Polyester of adipic acid with glycerol or | In compliance with the specifications |

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| | | pentaerythritol, esters with even numbered, unbranched C ₁₂ -C ₂₂ fatty acids | laid down in Annex V |
| 76845 | 031831-53-5 | Polyester of 1,4-butanediol with caprolactone | In compliance with the specifications laid down in Annex V |
| 77370 | 070142-34-6 | Polyethyleneglycol-30 dipolyhydroxystearate | |
| 79600 | 009046-01-9 | Polyethyleneglycol-tridecyl ether phosphate | SML = 5 mg/kg. For materials and articles intended for contact with aqueous foods only. In compliance with the specification laid down in Annex V |
| 80000 | 009002-88-4 | Polyethylene wax | |
| 81060 | 009003-07-0 | Polypropylene wax ⁷ | |

- (b) in the following lines the content of the columns 'Name' and 'Restrictions and/or specifications' is replaced by the following:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|--------------------------|--|
| (1) | (2) | (3) | (4) |
| '30080 | 004180-12-5 | Acetic acid, copper salt | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 35760 | 001309-64-4 | Antimony trioxide | SML = 0,04 mg/kg ⁽³⁹⁾ (expressed as Antimony) |
| 40580 | 000110-63-4 | 1,4-Butanediol | SML(T) = 5 mg/kg ⁽²⁴⁾ |

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| 42320 | 007492-68-4 | Carbonic acid, copper salt | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 45195 | 007787-70-4 | Copper bromide | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 45200 | 001335-23-5 | Copper iodide | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 53610 | 054453-03-1 | Ethylenediaminetetraacetic acid, copper salt | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 81515 | 087189-25-1 | Poly(zinc glycerolate) | SML(T) = 25 mg/kg ⁽³⁸⁾ (as Zinc) |
| 81760 | — | Powders, flakes and fibers of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 88640 | 008013-07-08 | Soybean oil, epoxidised | SML = 60 mg/kg. However in the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Commission Directive 91/321/EEC or containing processed cereal-based foods and baby foods for infants and young children as defined by Directive 96/5/EC, the SML is lowered to 30 mg/kg |

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| 89200 | 007617-31-4 | Stearic acid, copper salt | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 92030 | 010124-44-4 | Sulphuric acid, copper salt | SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as Copper) |
| 96190 | 020427-58-1 | Zinc hydroxide | SML(T) = 25 mg/kg ⁽³⁸⁾ (as Zinc) |
| 96240 | 001314-13-2 | Zinc oxide | SML(T) = 25 mg/kg ⁽³⁸⁾ (as Zinc) |
| 96320 | 001314-98-3 | Zinc sulphide | SML(T) = 25 mg/kg ⁽³⁸⁾ (as Zinc) ⁷ |

(c) the following lines are deleted:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|---|---|
| (1) | (2) | (3) | (4) |
| '30400 | — | Acetylated glycerides | |
| 38320 | 005242-49-9 | 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene | In compliance with the specifications laid down in Annex V' |

3. section B is amended as follows:

(a) the following lines are inserted in numerical order:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|---|---|
| (1) | (2) | (3) | (4) |
| '31500 | 025134-51-4 | Acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer | SML(T) = 6 mg/kg ⁽³⁶⁾ (expressed as acrylic acid) and SML = 0,05 mg/kg (expressed as acrylic acid, 2-ethylhexyl ester) |

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| 38505 | 351870-33-2 | cis-endo-Bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt | SML = 5 mg/kg. Not to be used with polyethylene in contact with acidic foods. Purity \geq 96 % |
| 38940 | 110675-26-8 | 2,4-Bis(dodecylthiomethyl)-6-methylphenol | SML(T) = 5 mg/kg ⁽¹⁶⁾ |
| 49595 | 057583-35-4 | Dimethyltin bis(ethylhexyl mercaptoacetate) | SML(T) = 0,18 mg/kg ⁽¹⁶⁾ (expressed as Tin) |
| 63940 | 008062-15-5 | Lignosulphonic acid | SML = 0,24 mg/kg and to be used only as dispersant for plastics dispersions |
| 66350 | 085209-93-4 | 2,2'-Methylenebis(4,6-di-tert-butylphenyl) lithium phosphate | SML = 5 mg/kg and SML(T) = 0,6 ⁽⁸⁾ (expressed as Lithium) |
| 67515 | 057583-34-3 | Monomethyltin tris(ethylhexyl mercaptoacetate) | SML(T) = 0,18 mg/kg ⁽¹⁶⁾ (expressed as Tin) |
| 69160 | 014666-94-5 | Oleic acid, cobalt salt | SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt) |
| 76681 | — | Polycyclopentadiene hydrogenated | SML = 5 mg/kg ⁽¹⁾ |
| 85950 | 037296-97-2 | Silicic acid, magnesium-sodium-fluoride salt | SML = 0,15 mg/kg (expressed as fluoride). Only to be used in layers of multilayers materials not coming into direct contact with food |

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| 95265 | 227099-60-7 | 1,3,5-Tris(4-benzoylphenyl)benzene | SML = 0,05 mg/kg' |
|-------|-------------|------------------------------------|-------------------|

(b) in the following lines the content of the columns 'Name' and 'Restrictions and/or specifications' is replaced by the following:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|--|---|
| (1) | (2) | (3) | (4) |
| 40020 | 110553-27-0 | 2,4-Bis(octylthiomethyl)-6 ⁴⁰ methylphenol | SML(T) = 5 mg/kg |
| 50160 | — | Di-n-octyltin bis(n-alkyl(C ₁₀ -C ₁₆)mercaptoacetate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50240 | 010039-33-5 | Di-n-octyltin bis(2-ethylhexyl maleate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50320 | 015571-58-1 | Di-n-octyltin bis(2-ethylhexyl mercaptoacetate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50360 | — | Di-n-octyltin bis(ethyl maleate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50400 | 033568-99-9 | Di-n-octyltin bis(isooctyl maleate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50480 | 026401-97-8 | Di-n-octyltin bis(isooctyl mercaptoacetate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50560 | — | Di-n-octyltin 1,4-butanediol bis(mercaptoacetate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50640 | 003648-18-8 | Di-n-octyltin dilaurate | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ |

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| | | | (expressed as Tin) |
| 50720 | 015571-60-5 | Di-n-octyltin dimaleate | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50800 | — | Di-n-octyltin dimaleate, esterified | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50880 | — | Di-n-octyltin dimaleate, polymers (n = 2-4) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 50960 | 069226-44-4 | Di-n-octyltin ethyleneglycol bis(mercaptoacetate) | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 51040 | 015535-79-2 | Di-n-octyltin mercaptoacetate | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 51120 | — | Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate | SML(T) = 0,006 mg/kg ⁽¹⁷⁾ (expressed as Tin) |
| 67180 | — | Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n-octyl ester | SML = 5 mg/kg ⁽¹⁾ |

(c) The following line is deleted:

| Reference No | CAS No | Name | Restrictions and/or specifications |
|--------------|-------------|----------------------------------|------------------------------------|
| (1) | (2) | (3) | (4) |
| ‘76680 | 068132-00-3 | Polycyclopentadiene hydrogenated | SML = 5 mg/kg ⁽¹⁾ |

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ANNEX III

In Part B of Annex V, the following lines are inserted in numerical order:

| Reference No | OTHER SPECIFICATIONS |
|--------------|--|
| ‘24903 | Syrups, hydrolysed starch, hydrogenated In compliance with the purity criteria for maltitol syrup E 965(ii) (Commission Directive 95/31/EC (OJ L 178, 28.7.1995, p. 1) as last amended by 2004/46/EC (OJ L 114, 21.04.2004, p. 15)) |
| 43480 | Charcoal, activated To be used only in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC ((OJ L 226, 22.9.1995, p. 1). Directive as last amended by Directive 2004/47/EC (OJ L 113, 20.4.2004, p. 24)) with exception of ash content which can be up to 10 % (w/w). |
| 64990 | Maleic anhydride-styrene, copolymer, sodium salt MW fraction < 1 000 is less than 0,05 % (w/w) |
| 67155 | Mixture of 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxazolyl) stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene Mixture obtained from the manufacturing process in the typical ratio of (58-62 %): (23-27 %): (13-17 %). |
| 76845 | Polyester of 1,4-butanediol with caprolactone MW fraction < 1 000 is less than 0,05 % (w/w) |
| 76815 | Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C12-C22 fatty acids MW fraction < 1 000 is less than 5 % (w/w) |
| 79600 | Polyethyleneglycol tridecyl ether phosphate Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono-and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether’ |

ANNEX IV

Annex VI is amended as follows:

1. the notes ⁽⁸⁾, ⁽¹⁴⁾ and ⁽¹⁶⁾ are replaced by the following:
 - ⁽⁸⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 38000, 42400, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.
 - ⁽¹⁴⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 44960, 68078, 69160, 82020 and 89170.
 - ⁽¹⁶⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 49595, 49600, 67520, 67515 and 83599.;
2. the following notes are added:
 - ⁽³⁵⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 25540 and 25550.
 - ⁽³⁶⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 10690, 10750, 10780, 10810, 10840, 11470, 11590, 11680, 11710, 11830, 11890, 11980 and 31500.
 - ⁽³⁷⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 20020, 20080, 20110, 20140, 20170, 20890, 21010, 21100, 21130, 21190, 21280, 21340 and 21460.
 - ⁽³⁸⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 81515, 96190, 96240 and 96320 as well as of salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. The same restriction for Zn applies to the names containing "... acid(s), salts" which appear in the lists, if the corresponding free acid(s) is (are) not mentioned.
 - ⁽³⁹⁾ Migration limit might be exceeded at very high temperature.
 - ⁽⁴⁰⁾ SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 38940 and 40020.

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- (1) OJ L 338, 13.11.2004, p. 4.
- (2) OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2004/19/EC (OJ L 71, 10.3.2004, p. 8).
- (3) OJ L 175, 4.7.1991, p. 35. Directive as last amended by Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37).
- (4) OJ L 49, 28.2.1996, p. 17. Directive as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33).
- (5) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).