

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 (max 4 %). To be used only as co-monomer (max 4 %) for

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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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Status: This is the original version (as it was originally adopted).

(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)

‘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	

Status: This is the original version (as it was originally adopted).

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

		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⁾

Status: This is the original version (as it was originally adopted).

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

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)

Status: This is the original version (as it was originally adopted).

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

95265	227099-60-7	1,3,5-Tris(4-benzoylphenyl)benzene	SML = 0,05 mg/kg'
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- (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)methylphenol	SML(T) = 5 mg/kg ⁽⁴⁰⁾
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⁾

Status: This is the original version (as it was originally adopted).

			(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⁾

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.