

ANNEX I

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

- (a) the following monomers and other starting substances are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15404	000652-67-5	1,4:3,6-Dianhydrosorbitol	SML = 5 mg/kg. Only for use as a co-monomer in poly(ethylene-co-isosorbide terephthalate)
19180	000099-63-8	Isophthalic acid dichloride	SML(T) = 5 mg/kg (43) (expressed as isophthalic acid)
26305	000078-08-0	Vinyltriethoxysilane	SML = 0,05 mg/kg. Only to be used as a surface treatment agent'

- (b) for the following monomers and starting substances, the content of the column 'Restrictions and/or specifications' is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'19150	000121-91-5	Isophthalic acid	SML(T) = 5 mg/kg (43)'

ANNEX II

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

- (1) Section A is amended as follows:

- (a) The following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'38875	002162-74-5	Bis(2,6-diisopropylphenyl)carbodiimide	SML = 0,05 mg/kg. For use behind a PET layer

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45703	491589-22-1	cis-1,2-Cyclohexanedicarboxylic acid, calcium salt	SML = 5 mg/kg
48960	—	9,10-dihydroxy stearic acid and its oligomers	SML = 5 mg/kg
55910	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates	
60025	—	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene	In compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.
62280	009044-17-1	Isobutylene-butene copolymer	
70480	000111-06-8	Palmitic acid, butyl ester	
76463	—	Polyacrylic acid, salts	SML(T) = 6 mg/kg (36) (for acrylic acid)
76723	167883-16-1	Polydimethylsiloxane terminated, 3-aminopropyl polymer with dicyclohexylmethane diisocyanate	In compliance with the specifications laid down in Annex V
76725	661476-41-1	Polydimethylsiloxane terminated, 3-aminopropyl polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	In compliance with the specifications laid down in Annex V
77732	—	Polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-	SML = 0,05 mg/kg. Only for use in PET

		methoxyphenyl) acrylate	
77733	—	Polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77897	—	Polyethyleneglycol monoalkylether (linear and branched, C ₈ -C ₂₀) sulphate, salts	SML = 5 mg/kg
89120	000123-95-5	Stearic acid, butyl ester	
95858	—	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.'

- (b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	SML = 0,05 mg/kg
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0,5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an anti-microbial effect

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at the surface of the polymer or on the food itself.'

(c) the following additives are deleted:

Ref. 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'	

(2) Section B is amended as follows:

(a) the following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34130	—	Alkyl, linear with even number of carbon atoms (C ₁₂ -C ₂₀) dimethylamines	SML = 30 mg/kg
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	SML = 6 mg/kg'

(b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)	In compliance with the specifications laid down in Annex V'

ANNEX III

In Annex IVa to Directive 2002/72/EC the following substances are inserted in the appropriate numerical order:

Ref. No	CAS No	Name
'34130	—	Alkyl, linear with even number of carbon atoms (C12-C20) dimethylamines
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]'

ANNEX IV

In Part B of Annex V to Directive 2002/72/EC the following new specifications are inserted, in the appropriate numerical order:

Ref. No	Other specifications
'60025	Specifications: — Minimum viscosity (at 100 °C) = 3,8 cSt — Average Mw > 450
76723	Specifications: The fraction with molecular weight below 1 000 should not exceed 1,5 % w/w
76725	Specifications: The fraction with molecular weight below 1 000 should not exceed 1 % w/w
95858	Specifications: — Average molecular weight not less than 350 — Viscosity at 100 °C min 2,5 cSt — Content of hydrocarbons with carbon number less than 25, not more than 40 % w/w'

ANNEX V

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

- (1) Note (36) is replaced by the following:

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(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, 31500 and 76463.

(2) Note (43) is added:

(⁴³) 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 19150 and 19180.