

COMMISSION REGULATION (EC) No 975/2009**of 19 October 2009****amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs****(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,

Whereas:

- (1) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs ⁽²⁾ establishes a Community list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. Recently additional monomers and starting substances have received a favourable scientific evaluation by the European Food Safety Authority (the Authority) and should now be added to the existing list.
- (2) Directive 2002/72/EC also contains a Community list of additives which may be used for the manufacture of plastic materials and articles. Recently additional additives have received a favourable scientific evaluation

by the Authority and should now be added to the existing list.

- (3) Directive 2002/72/EC should therefore be amended accordingly.
- (4) According to Article 4(1) of Directive 2002/72/EC, the Community list of additives contained in Annex III to that Directive will become a positive list from 1 January 2010. Consequently, the titles in Annex III to that Directive should no longer refer to an 'incomplete' list of additives.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 October 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ OJ L 220, 15.8.2002, p. 18.

ANNEX I

In section A to Annex II to Directive 2002/72/EC the following lines are inserted in the table in numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'14627	0000117-21-5	3-chlorophthalic anhydride	SML = 0,05 mg/kg expressed as 3-chlorophthalic acid
14628	0000118-45-6	4-chlorophthalic anhydride	SML = 0,05 mg/kg expressed as 4-chlorophthalic acid
14876	0001076-97-7	1,4-cyclohexanedicarboxylic acid	SML = 5 mg/kg Only to be used for manufacture of polyesters
18117	0000079-14-1	glycolic acid	For indirect food contact only, behind a polyethylene terephthalate (PET) layer
19965	0006915-15-7	malic acid	Only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis
21498	0002530-85-0	[3-(methacryloxy)propyl]trimethoxysilane	SML = 0,05 mg/kg Only to be used as a surface treatment agent of inorganic fillers'

ANNEX II

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

(1) The word 'incomplete' is deleted from the general title of Annex III as well as from the titles of Sections A and B.

(2) In section A the following lines are inserted in numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'30607	—	acids, C ₂ -C ₂₄ , aliphatic, linear, mono-carboxylic, from natural oils and fats, lithium salt	SML(T) = 0,6 mg/kg (expressed as Lithium) ⁽⁸⁾
33105	0146340-15-0	alcohols, C ₁₂ -C ₁₄ secondary, β-(2-hydroxyethoxy), ethoxylated	SML = 5 mg/kg ⁽⁴⁴⁾
33535	0152261-33-1	α-alkenes(C ₂₀ -C ₂₄) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	Not to be used for articles in contact with fatty foods for which simulant D is laid down Not to be used in contact with alcoholic foods
38550	0882073-43-0	bis(4-propylbenzylidene)propylsorbitol	SML = 5 mg/kg (including the sum of its hydrolysis products)
40155	0124172-53-8	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylene-diamine	SML = 0,05 mg/kg ⁽¹⁾ ⁽⁴⁴⁾
49080	0852282-89-4	N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione	SML = 0,05 mg/kg ⁽³⁹⁾ ⁽⁴⁵⁾ ⁽⁴⁶⁾ Only for use in polyethylene terephthalate (PET)
60027	—	hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12 000)	Not to be used for articles in contact with fatty foods for which simulant D is laid down. In compliance with the specification laid down in Annex V
62215	0007439-89-6	iron	SML = 48 mg/kg
68119	—	neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid	SML = 5 mg/kg Not to be used for articles in contact with fatty foods for which simulant D is laid down.
72141	0018600-59-4	2,2'-(1,4-phenylene)bis[4H-3,1-benz-oxazin-4-one]	SML = 0,05 mg/kg (including the sum of its hydrolysis products)
76807	00073018-26-5	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	SML = 30 mg/kg
77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	SML = 1,8 mg/kg In compliance with the specification laid down in Annex V
80077	0068441-17-8	polyethylene waxes, oxidised	SML = 60 mg/kg

(1)	(2)	(3)	(4)
80350	0124578-12-7	poly(12-hydroxystearic acid)-polyethylenimine copolymer	Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w. In compliance with the specification laid down in Annex V
80480	0090751-07-8; 0082451-48-7	poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	SML = 5 mg/kg ⁽⁴⁷⁾ In compliance with the specification laid down in Annex V
80510	1010121-89-7	poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oley-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	Only to be used as a polymerisation production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)
91530	—	sulphosuccinic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts	SML = 5 mg/kg
91815	—	sulphosuccinic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts	SML = 2 mg/kg
92200	0006422-86-2	terephthalic acid, bis(2-ethylhexyl)ester	SML = 60 mg/kg
92470	0106990-43-6	N,N',N'',N'''-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine	SML = 0,05 mg/kg
92475	0203255-81-6	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid	SML = 5 mg/kg (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products)
93450	—	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	In compliance with the specification laid down in Annex V
94000	0000102-71-6	triethanolamine	SML = 0,05 mg/kg (including the hydrochloride adduct)
94425	0000867-13-0	triethyl phosphonoacetate	Only for use in polyethylene terephthalate (PET)
94985	—	trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid	SML = 5 mg/kg Not to be used for articles in contact with fatty food for which simulant D is laid down'

ANNEX III

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

Ref. No	CAS No	Name
'49080	852282-89-4	N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione
72141	0018600-59-4	2,2'-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]
76807	0007308-26-5	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol
92475	0203255-81-6	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid'

ANNEX IV

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

Ref. No	Other specifications
'60027	hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12 000) Average molecular weight not less than 440 Da Viscosity at 100 °C not less than 3,8 cSt ($3,8 \times 10^{-6} \text{ m}^2/\text{s}$)
77708	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary ($\text{C}_8\text{-C}_{22}$) alcohols Maximum residual quantity of ethylene oxide in the material or article = 1 mg/kg
80350	poly(12-hydroxystearic acid)-polyethyleneimine copolymer Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine
80480	poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino] Average molecular weight not less than 2 400 Da Residual content of morpholine $\leq 30 \text{ mg/kg}$, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine $< 15\,000 \text{ mg/kg}$, and of 2,4-dichloro-6-morpholino-1,3,5-triazine $\leq 20 \text{ mg/kg}$
93450	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt] The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w

ANNEX V

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

1. The note (8) is 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 Ref. Nos: 24886, 62020, 30607, 38000, 42400, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.'

2. The following notes are added:

⁽⁴⁴⁾ The SML could be exceeded from polyolefins.

⁽⁴⁵⁾ The SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.

⁽⁴⁶⁾ The SML could be exceeded in contact with foods with high alcoholic content.

⁽⁴⁷⁾ The SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods.'
