
Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

ANNEX I

Substances

1. Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids

Table 1 contains the following information:

Column 1 (FCM substance No): the unique identification number of the substance

Column 2 (Ref. No): the EEC packaging material reference number

Column 3 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column 4 (Substance Name): the chemical name

Column 5 (Use as additive or polymer production aid (PPA) (yes/no)): an indication if the substance is authorised to be used as additive or polymer production aid (yes) or if the substance is not authorised to be used as additive or polymer production aid (no). If the substance is only authorised as PPA it is indicated (yes) and in the specifications the use is restricted to PPA.

Column 6 (Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)): an indication if the substance is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (no). If the substance is authorised as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

Column 7 (FRF applicable (yes/no)): an indication if for the substance the migration results can be corrected by the Fat Consumption Reduction Factor (FRF) (yes) or if they cannot be corrected by the FRF (no).

Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 9 (SML(T) [mg/kg] (group restriction No)): contains the identification number of the group of substances for which the group restriction in Column 1 in Table 2 of this Annex applies.

Column 10 (Restrictions and specifications): contains other restrictions than the specific migration limit specifically mentioned and it contains specifications related to the substance. In case detailed specifications are set out a reference to Table 4 is included.

Column 11 (Notes on verification of compliance): contains the Notes number which refers to the detailed rules applicable for verification of compliance for this substance included in Column 1 in Table 3 of this Annex.

If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

If in Column 8 the specific migration limit is non-detectable (ND) a detection limit of 0,01 mg substance per kg food is applicable unless specified differently for an individual substance.

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TABLE 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer product aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications (Group restriction No)	Notes on certification of compliance
1	12310	0266309	albumin	no	yes	no				
2	12340	—	albumin coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₂₂)	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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5	25360	—	trialkyl(C ₆ -C ₁₅)acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylates acid, salts	yes	no	no				
8	30401	—	acetylates mono- and diglycerides of fatty acids	yes	no	no		(32)		
9	30610	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			esters (branched fatty acids at naturally occurring levels are included)							
10	30612	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no				
11	30960	—	acids, aliphatic, monocarboxylic (C ₆ -C ₂₂), esters with polyglycerol	yes	no	no				
12	31328	—	acids, fatty, from animal or vegetable food fats and oils	yes	no	no				
13	33120	—	alcohols, aliphatic, monohydric,	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			saturated, linear, primary (C ₄ - C ₂₄)							
14	33801	—	n-alkyl(C ₁₀ - C ₁₃)benzenesulphonic acid	yes	no	no	30			
15	34130	—	alkyl, linear with even number of carbon atoms (C ₁₂ - C ₂₀) dimethylamines	yes	no	yes	30			
16	34230	—	alkyl(C ₈ - C ₂₂)sulphonic acids	yes	no	no	6			
17	34281	—	alkyl(C ₈ - C ₂₂)sulphuric acids, linear, primary with an even number of carbon atoms	yes	no	no				
18	34475	—	aluminium, calcium hydroxide phosphite, hydrate	yes	no	no				
19	39090	—	N,N- bis(2-	yes	no	no		(7)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			hydroxyethyl)alkyl(C ₈ -C ₁₈)amine						
20	39120	—	N,N-bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine hydrochlorides	yes	no	no		(7)	SML(T) expressed excluding HCl
21	42500	—	carbonic acid, salts	yes	no	no			
22	43200	—	castor oil, mono- and diglycerides	yes	no	no			
23	43515	—	chlorides of choline esters of coconut oil fatty acids	yes	no	no	0,9		(1)
24	45280	—	cotton fibers	yes	no	no			
25	45440	—	cresols, butylated, styrenated	yes	no	no	12		
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-	yes	no	no	5		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)							
27	48960	—	9,10-dihydroxy stearic acid and its oligomers	yes	no	no	5			
28	50160	—	di-n-octyltin bis(n-alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	yes	no	no		(10)		
29	50360	—	di-n-octyltin bis(ethyl maleate)	yes	no	no		(10)		
30	50560	—	di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	yes	no	no		(10)		
31	50800	—	di-n-octyltin dimaleate, esterified	yes	no	no		(10)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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32	50880	—	di-n-octyltin dimaleate, polymers (n = 2-4)	yes	no	no		(10)		
33	51120	—	di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	yes	no	no		(10)		
34	54270	—	ethylhydroxyethylcellulose	yes	no	no				
35	54280	—	ethylhydroxypropylcellulose	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and oils, hydrogenated, from animal or vegetable food sources	yes	no	no				
38	55520	—	glass fibers	yes	no	no				
39	55600	—	glass microballs	yes	no	no				
40	56360	—	glycerol esters with	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			acetic acid						
41	56486	—	glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C ₁₄ -C ₁₈) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C ₁₆ -C ₁₈)	yes	no	no			
42	56487	—	glycerol, esters with butyric acid	yes	no	no			
43	56490	—	glycerol, esters with erucic acid	yes	no	no			

a [OJ L 302, 19.11.2005, p. 28.](#)

b [OJ L 330, 5.12.1998, p. 32.](#)

c [OJ L 253, 20.9.2008, p. 1.](#)

d [OJ L 226, 22.9.1995, p. 1.](#)

e [OJ L 158, 18.6.2008, p. 17.](#)

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44	56495	—	glycerol esters with 12-hydroxystearic acid	yes	no	no				
45	56500	—	glycerol esters with lauric acid	yes	no	no				
46	56510	—	glycerol esters with linoleic acid	yes	no	no				
47	56520	—	glycerol esters with myristic acid	yes	no	no				
48	56535	—	glycerol esters with nonanoic acid	yes	no	no				
49	56540	—	glycerol esters with oleic acid	yes	no	no				
50	56550	—	glycerol esters with palmitic acid	yes	no	no				
51	56570	—	glycerol esters with propionic acid	yes	no	no				

a [OJ L 302, 19.11.2005, p. 28.](#)

b [OJ L 330, 5.12.1998, p. 32.](#)

c [OJ L 253, 20.9.2008, p. 1.](#)

d [OJ L 226, 22.9.1995, p. 1.](#)

e [OJ L 158, 18.6.2008, p. 17.](#)

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52	56580	—	glycerol esters with ricinoleic acid	yes	no	no				
53	56585	—	glycerol esters with stearic acid	yes	no	no				
54	57040	—	glycerol monooleate, ester with ascorbic acid	yes	no	no				
55	57120	—	glycerol monooleate, ester with citric acid	yes	no	no				
56	57200	—	glycerol monopalmitate, ester with ascorbic acid	yes	no	no				
57	57280	—	glycerol monopalmitate, ester with citric acid	yes	no	no				
58	57600	—	glycerol monostearate, ester with ascorbic acid	yes	no	no				
59	57680	—	glycerol monostearate,	yes	no	no				

a [OJ L 302, 19.11.2005, p. 28.](#)

b [OJ L 330, 5.12.1998, p. 32.](#)

c [OJ L 253, 20.9.2008, p. 1.](#)

d [OJ L 226, 22.9.1995, p. 1.](#)

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			ester with citric acid						
60	58300	—	glycine, salts	yes	no	no			
62	64500	—	lysine, salts	yes	no	no			
63	65440	—	manganese pyrophosphate	yes	no	no			
64	66695	—	methylhydroxymethylcellulose	yes	no	no			
65	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	yes	no	no			Not more than 0,05 % (w/w) (quantity of substance used/ quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %): (23-27 %): (13-17 %).
66	67600	—	mono-n-octyltin tris(alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	yes	no	no		(11)	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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67	67840	—	montanic acids and/or their esters with ethyleneglycol and/or with 1,3- butanediol and/or with glycerol	yes	no	no			
68	73160	—	phosphoric acid, mono- and di- n-alkyl (C ₁₆ and C ₁₈) esters	yes	no	yes	0,05		
69	74400	—	phosphoric acid, tris(nonyl- and/or dinonylphenyl) ester	yes	no	yes	30		
70	76463	—	polyacrylic acid, salts	yes	no	no		(22)	
71	76730	—	polydimethylsiloxane, γ- hydroxypropylated	yes	no	no	6		
72	76815	—	polyester of adipic acid with glycerol or pentaerythritol,	yes	no	no		(32)	The fraction with molecular weight below 1 000 Da

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			esters with even numbered, unbranched C ₁₂ -C ₂₂ fatty acids					should not exceed 5 % (w/w)
73	76866	—	polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol	yes	no	yes	(31) (32)	
74	77440	—	polyethyleneglycol diricinoleate	yes	no	yes	42	
75	77702	—	polyethyleneglycol esters of	yes	no	no		

a [OJ L 302, 19.11.2005, p. 28.](#)

b [OJ L 330, 5.12.1998, p. 32.](#)

c [OJ L 253, 20.9.2008, p. 1.](#)

d [OJ L 226, 22.9.1995, p. 1.](#)

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			aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates						
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano-3-(4-hydroxy-3-methoxyphenyl) acrylate	no	no	0,05		Only for use in PET	
77	77733	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	no	no	0,05		Only for use in PET	
78	77897	—	polyethylene glycol monoalkylether (linear and branched,	no	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			C ₈ - C ₂₀) sulphate, salts						
79	80640	—	polyoxyalkyl (C ₂ - C ₄) dimethylpolysiloxane	no	no				
80	81760	—	powders flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	yes	no	no			
81	83320	—	propylhydroxyethylcellulose	yes	no	no			
82	83325	—	propylhydroxyethylcellulose	yes	no	no			
83	83330	—	propylhydroxypropylcellulose	yes	no	no			
84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no			
85	85610	—	silicates, natural, silanated (with the exception	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			of asbestos)							
86	86000	—	silicic acid, silylated	yes	no	no				
87	86285	—	silicon dioxide, silanated	yes	no	no				
88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no		(2)		
90	92195	—	taurine, salts	yes	no	no				
91	92320	—	tetradecyl polyethyleneglycol(EO = 3-8) ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclic bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05			Not to be used for articles in contact with fatty foods for which simulant D is

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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									laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less than 2,5 cSt (2,5 × 10 ⁻⁶ m ² /s). Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w).
94	95859	—	waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	yes	no	no			Average molecular weight not less than 500 Da. Viscosity at 100 °C not
a	OJ L 302, 19.11.2005, p. 28.								
b	OJ L 330, 5.12.1998, p. 32.								
c	OJ L 253, 20.9.2008, p. 1.								
d	OJ L 226, 22.9.1995, p. 1.								
e	OJ L 158, 18.6.2008, p. 17.								

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									less than 11 cSt ($11 \times 10^{-6} \text{ m}^2/\text{s}$). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
95	95883	—	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	yes	no	no			Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt ($8,5 \times 10^{-6} \text{ m}^2/\text{s}$). Content of mineral hydrocarbons with Carbon number

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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									less than 25, not more than 5 % (w/w).
96	95920	—	wood flour and fibers, untreated	yes	no	no			
97	72081/10	—	petroleum hydrocarbon resins (hydrogenated)	yes	no	no			Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C,

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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									as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: — Viscosity at 120 °C: > 3 Pa.s, — Softening point: > 95 °C as determined by ASTM Method E 28-67, — Bromine number: < 40 (ASTM D1159), — The colour of a 50 % solution in toluene < 11
a	OJ L 302, 19.11.2005, p. 28.								
b	OJ L 330, 5.12.1998, p. 32.								
c	OJ L 253, 20.9.2008, p. 1.								
d	OJ L 226, 22.9.1995, p. 1.								
e	OJ L 158, 18.6.2008, p. 17.								

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										on the Gardner scale, Residual aromatic monomer ≤ 50 ppm,
98	17260	0000050600-0	Formaldehyde	yes	no		(15)			
	54880									
99	19460	0000050621-6	Lactic acid	yes	yes	no				
	62960									
100	24490	0000050507-0	Sorbitol	yes	yes	no				
	88320									
101	36000	0000050680-7	Ascorbic acid	yes	no	no				
102	17530	0000050900-7	Glycerol	no	yes	no				
103	18100	0000056816-6	Glycerol	yes	yes	no				
	55920									
104	58960	0000057102-0	Decyltrimethylammonium bromide	yes	yes	no	6			
105	22780	0000057101-1	Phthalic acid	yes	yes	no				
	70400									
106	24550	0000057104-4	Stearic acid	yes	yes	no				
	89040									
107	25960	0000057136-6	Urea	no	yes	no				
108	24880	0000057500-0	Sorbitol	no	yes	no				
109	23740	0000057153-6	1,2-propanediol	yes	yes	no				
	81840									
110	93520	0000059002-9 0010191400-0	Hydroxyphenol	yes	no	no				
111	53600	0000060004-4	Benzoic acid	yes	no	no				

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112	64015	0000060130-3	lactic acid	yes	no	no			
113	16780	0000064177-5	ethanol	yes	yes	no			
	52800								
114	55040	0000064181-6	formic acid	yes	no	no			
115	10090	0000064191-7	acetic acid	yes	yes	no			
	30000								
116	13090	0000065181-0	benzoic acid	yes	yes	no			
	37600								
117	21550	0000067141-1	methanol	no	yes	no			
118	23830	0000067263-0	propanol	yes	yes	no			
	81882								
119	30295	0000067264-1	acetone	yes	no	no			
120	49540	0000067268-1	diethyl sulphoxide	yes	no	no			
121	24270	0000069271-5	salicylic acid	yes	yes	no			
	84640								
122	23800	0000071123-8	propanol	no	yes	no			
123	13840	0000071136-3	butanol	no	yes	no			
124	22870	0000071141-0	pentanol	no	yes	no			
125	16950	0000074281-1	ethylene	no	yes	no			
126	10210	0000074286-2	ethylene	no	yes	no			
127	26050	0000075011-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product
128	10060	0000075071-0	acetaldehyde	yes	no	no		(1)	
129	17020	0000075211-8	ethylene oxide	no	yes	no	ND		1 mg/kg in (10)

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								final product	
130	26110	0000075354	vinylidene chloride	yes	no	ND			(1)
131	48460	0000075437-6	1,1-difluoroethane	yes	no	no			
132	26140	0000075387	vinylidene fluoride	yes	no	5			
133	14380 23155	0000075446	vinylidene chloride	yes	no	ND		1 mg/kg in final product	(10)
134	43680	0000075456	1,1-dichloro-1,1-difluoroethane	yes	no	6		Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	0000075569	ethylene oxide	yes	no	ND		1 mg/kg in final product	
136	41680	0000076222	hexachlorocyclopentadiene	yes	no	no			(3)
137	66580	0000077262-3	1,1'-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	yes	no	yes	(5)		
138	93760	0000077407	butyl acetyl citrate	yes	no	no	(32)		
139	14680 44160	0000077922	citric acid	yes	yes	no			
140	44640	0000077930	citric acid, triethyl ester	yes	no	no	(32)		

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141	13380	0000077199-6	199-6 trimethylolpropane	yes	yes	no	6		
	25600								
	94960								
142	26305	0000078084-0	8084-0 triethoxysilanes	no	no	no	0,05	Only to be used as a surface treatment agent	(1)
143	62450	0000078178-4	178-4 isopentane	yes	no	no			
144	19243	0000078279-5	279-5 methyl-1,3-butadiene	no	yes	no	ND		1 mg/kg in final product
	21640								
145	10630	0000079006-1	006-1 amide	yes	yes	no	ND		
146	23890	0000079009-1	009-1 acid	yes	yes	no			
	82000								
147	10690	0000079011-1	011-1 acetic acid	no	yes	no		(22)	
148	14650	0000079118-9	118-9 trifluoroethylene	no	no	no	ND		(1)
149	19990	0000079130-0	130-0 methacrylamide	yes	yes	no	ND		
150	20020	0000079141-1	141-1 methacrylic acid	yes	yes	no		(23)	
151	13480	0000080205-7	205-7 bis(4-hydroxyphenyl)propane	no	yes	no	0,6		
	13607								
152	15610	0000080407-9	407-9 dichlorodiphenyl sulphone	no	yes	no	0,05		
153	15267	0000080408-0	408-0 diaminodiphenyl sulphone	no	yes	no	5		
154	13617	0000080409-1	409-1 dihydroxydiphenyl sulphone	no	yes	no	0,05		
	16090								

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155	23470	0000080e56-8	pinene	no	yes	no				
156	21130	0000080e62-16	acrylic acid, methyl ester	no	yes	no		(23)		
157	74880	00000847-14	phthalic acid, dibutyl ester	yes	no	no	0,3	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in polyolefins in concentrations up to 0,05 % in the final product.
158	23380	00000851-10	phthalic anhydride	yes	yes	no				
	76320									
159	74560	00000851-17	phthalic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a)	(7) plasticiser in

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										(b)	repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by
a	OJ L 302, 19.11.2005, p. 28.										
b	OJ L 330, 5.12.1998, p. 32.										
c	OJ L 253, 20.9.2008, p. 1.										
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									(c)	Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
160	84800	0000087	18-3 salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
161	92160	0000087	16-9 phthalic acid	yes	no	no				
162	65520	0000087	7-8 nitrophenol	yes	no	no				
163	66400	0000088	22-4 methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088	26-6 aminobenzamide	yes	no	no	0,05		Only for use in PET for water and beverages	
165	23200 74480	0000088	09-3 phthalic acid	yes	yes	no				
166	24057	0000089	32-7 mellitic anhydride	yes	yes	no	0,05			

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167	25240	000009	1208-7 toluene diisocyanate	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	000009	1274-9 diamino-6- phenyl-1,3,5- triazine	no	yes	no	5			(1)
169	16240	000009	1397-4 dimethyl-4,4'- diisocyanatobiphenyl	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
170	16000	000009	2488-6 dihydroxybiphenyl	no	yes	no	6			
171	38080	000009	3582-3 benzoic acid, methyl ester	yes	no	no				
172	37840	000009	3582-0 benzoic acid, ethyl ester	yes	no	no				
173	60240	000009	4413-3 hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	000009	5648-7 cresol	no	yes	no				
175	20050	000009	60516-6 methacrylic acid, allyl ester	no	yes	no	0,05			

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176	11710	000009633	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	000009649	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	
178	92800	000009649	2,2,4,4-tetrakis(6-tert-butyl-3-methylphenol)propane	yes	no	yes	0,48			
179	48800	000009722	4,4'-dihydroxy-5,5'-dichlorodiphenylmethane	yes	no	yes	12			
180	17160	000009753	phenol	no	yes	no	ND			
181	20890	000009762	methacrylic acid, ethyl ester	no	yes	no		(23)		
182	19270	000009765	acetic acid	no	yes	no				

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183	21010	0000097	8619-4	acrylic acid, isobutyl ester	yes	no		(23)		
184	20110	0000097	8814-4	acrylic acid, butyl ester	yes	no		(23)		
185	20440	0000097	9016-4	acrylic acid, diester with ethyleneglycol	yes	no	0,05			
186	14020	0000098	4514-4	no butylphenol	yes	no	0,05			
187	22210	0000098	883-9	no methylstyrene	yes	no	0,05			
188	19180	0000099	63-8	isophthalic acid dichloride	yes	no		(27)		
189	60200	0000099	9476-3	yes hydroxybenzoic acid, methyl ester	no	no				
190	18880	0000099	996-7	no hydroxybenzoic acid	yes	no				
191	24940	0000100	1020-9	isophthalic acid dichloride	yes	no		(28)		
192	23187	—	—	phthalic acid	no	yes		(28)		
193	24610	0000100	342-5	styrene	no	yes				
194	13150	0000100	512-1	benzyl alcohol	no	yes				
195	37360	0000100	527-7	benzaldehyde	no	no				(3)
196	18670	0000100	607-0	hexamethylenetetramine	no	no		(15)		

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	59280								
197	20260	00001014319	methacrylic acid, cyclohexyl ester	yes	no	0,05			
198	16630	00001016818	4,4'-diphenylmethane diisocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
199	24073	00001019019	epichlorohydrin diglycidyl ether	yes	no	ND		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	(8)
200	51680	00001020819	diphenylthiourea	yes	no	yes	3		
201	16540	00001024010	diphenyl carbonate	yes	no	0,05			

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202	23070	0000102433-6	phenylenedioxydiacetic acid	no	yes	no	0,05			(1)
203	13323	0000102440-9	bis(2-hydroxyethoxy)benzene	no	yes	no	0,05			
204	25180	0000102560-3	'N'-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
	92640									
205	25385	0000102670-5	Hydramine	no	yes	no			40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. Only to be used in hydrogels intended for non-direct food contact use.	
206	11500	0000103211-6	acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05			
207	31920	0000103211-6	acrylic acid, bis(2-	yes	no	yes	18	(32)		(2)

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			ethylhexyl ester						
208	18898	000010339042	4-hydroxyphenyl acetamide	no	yes	no	0,05		
209	17050	0000104276-7	ethyl-1-hexanol	no	yes	no	30		
210	13390	0000105408-8	bis(hydroxymethyl)cyclohexane	no	yes	no			
	14880								
211	23920	0000105384	acrylic acid, vinyl ester	no	yes	no		(1)	
212	14200	0000105602	ε-caprolactam	yes	yes	no		(4)	
	41840								
213	82400	0000105162-4	propyleneglycol dioleate	yes	no	no			
214	61840	0000106124-9	hydroxystearic acid	yes	no	no			
215	14170	0000106016	butyric anhydride	no	yes	no			
216	14770	0000106044-5	cresol	no	yes	no			
217	15565	0000106146-7	dichlorobenzene	no	yes	no	12		
218	11590	0000106063	acrylic acid, isobutyl ester	no	yes	no		(22)	
219	14570	0000106089	chloroethanol	yes	yes	no	ND		1 mg/kg in final product
	16750								
220	20590	0000106042	acrylic acid, methacrylic acid,	yes	yes	no	0,02		(10)

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			2,3-epoxypropyl ester						
221	40570	000010697-8	butane	yes	no	no			
222	13870	0000106498-9	butene	no	yes	no			
223	13630	000010699-0	butadiene	no	yes	no	ND		1 mg/kg in final product
224	13900	0000107291-7	butene	no	yes	no			
225	12100	000010711-1	butyl acrylate	yes	no	no	ND		
226	15272	000010715-1	butyl diamine	yes	no	no	12		
	16960								
227	16990	000010717-1	ethylene glycol	yes	no	no	(2)		
	53650								
228	13690	000010718-0	butanediol	no	yes	no			
229	14140	000010719-1	butyric acid	no	yes	no			
230	16150	000010810-1	butylaminoethanol	yes	no	no	18		
231	10120	000010805-4	butyl acrylate, vinyl ester	no	yes	no	12		
232	10150	000010824-7	butyl acrylate anhydride	yes	yes	no			
	30280								
233	24850	000010810-1	butyl acrylate anhydride	no	yes	no			
234	19960	000010811-1	butyl acrylate anhydride	no	yes	no	(3)		
235	14710	000010879-4	cresol	no	yes	no			
236	23050	000010845-2	phenylenediamine	no	yes	no	ND		

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237	15910	0000108143	1,3-dihydroxybenzene	no	yes	no	2,4		
	24072								
238	18070	0000108554	sebacic anhydride	no	yes	no			
239	19975	0000108274	2,4,6-triamino-1,3,5-triazine	yes	yes	no	30		
	25420								
	93720								
240	45760	0000108918	hexylamine	no	no	no			
241	22960	0000108952	phenol	no	yes	no			
242	85360	0000109548	sebacic acid, dibutyl ester	yes	no	no		(32)	
243	19060	0000109556	isobutyl vinyl ether	no	yes	no	0,05		(10)
244	71720	0000109660	pentene	yes	no	no			
245	22900	0000109167	1-pentene	no	yes	no	5		
246	25150	0000109499	2,5-dimethylfuran	yes	no	no	0,6		
247	24820	0000110156	succinic acid	yes	yes	no			
	90960								
248	19540	0000110167	maleic acid	yes	yes	no		(3)	
	64800								
249	17290	0000110178	fumaric acid	yes	yes	no			
	55120								
250	53520	0000110305	N,N'-ethylenebisstearamide	yes	no	no			
251	53360	0000110306	N,N'-ethylenebisoleamide	yes	no	no			
252	87200	0000110341	sebacic acid	yes	no	no			
253	15250	0000110160	1,4-diaminobutane	no	yes	no			

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254	13720 40580	0000110164-4	butanediol	yes	yes	no		(30)		
255	25900	0000110188-3	hexane	no	yes	no	5			
256	18010 55680	0000110204-1	Malic acid	yes	yes	no				
257	13550 16660 51760	0000110209-5	propylene glycol	yes	yes	no				
258	70480	0000110208-1	Malic acid, butyl ester	yes	no	no				
259	58720	0000110218-1	heptanoic acid	yes	no	no				
260	24280	0000110220-6	isobutyric acid	no	yes	no				
261	15790	0000110240-0	dodecyltrimethylammonium	yes	yes	no	5			
262	35284	0000110241-1	(2-aminoethyl)ethanolamine	yes	no	no	0,05			Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind

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									a PET layer.
263	13326	0000111466-0	ethylene glycol	yes	no		(2)		
	15760								
	47680								
264	22660	0000111466-0	octene	no	yes	no	15		
265	22600	0000111487-5	octanol	no	yes	no			
266	25510	0000112476-0	ethylene glycol	yes	no				
	94320								
267	15100	0000112430-1	decanol	no	yes	no			
268	16704	0000112441-4	dodecene	no	yes	no	0,05		
269	25090	0000112607-0	ethylene glycol	yes	no				
	92350								
270	22763	0000112801-0	acid	yes	yes	no			
	69040								
271	52720	0000112845-0	amide	yes	no	no			
272	37040	0000112856-0	benzoic acid	yes	no	no			
273	52730	0000112867-0	acid	yes	no	no			
274	22570	0000112969-0	decyl isocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115007-0	polyene	no	yes	no			
276	19000	0000115107-0	isobutene	no	yes	no			

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277	18280	0000115276	2,6-chloroendomethylene tetrahydrophthalic anhydride	yes	no	ND			
278	18250	0000115286	2,6-chloroendomethylene tetrahydrophthalic acid	yes	no	ND			
279	22840	0000115775	7,7-aryloxybis(2-ethylhexyl)phthalic acid, bis(2-ethylhexyl) ester	yes	no				
	71600								
280	73720	0000115906	8-phosphoric acid, trichloroethyl ester	yes	no	ND			
281	25120	0000116443	1,1-difluoroethylene	yes	no	0,05			
282	18430	0000116454	1,1-difluoro-2-propylene	yes	no	ND			
283	74640	0000117017	phthalic acid, bis(2-ethylhexyl) ester	yes	no	1,5	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in concentrations up to 0,1 % in the final product.
284	84880	0000119368	salicylic acid,	yes	no	30			

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			methyl ester						
285	66480	0000119247-1	yes methylene bis(4-methyl-6-tert-butylphenol)	no	yes		(13)		
286	38240	0000119612-9	benzophenone	no	yes	0,6			
287	60160	0000120447-8	yes hydroxybenzoic acid, ethyl ester	no	no				
288	24970	0000120612-1	terephthalic acid, dimethyl ester	yes	no				
289	15880	0000120480-9	no 1,2-dihydroxybenzene	yes	no	6			
	24051								
290	55360	0000121710-0	yes lactic acid, propyl ester	no	no		(20)		
291	19150	0000121905-1	isophthalic acid	yes	no		(27)		
292	94560	0000122410-3	propylamine	yes	no	5			
293	23175	0000122510-5	phosphoric acid, triethyl ester	yes	no	ND		1 mg/kg in final product	(1)
294	93120	0000123428-1	yes dipropionic acid, didodecyl ester	no	yes		(14)		
295	15940	0000123134-9	yes 1,4-dihydroxybenzene	yes	no	0,6			
	18867								
	48620								

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296	23860	00001233860	3860 hexanaldehyde	yes	no			
297	23950	00001233950	3950 phthalic anhydride	no	yes	no		
298	14110	00001234110	4110 7-oxoheptanaldehyde	yes	no			
299	63840	00001236384	6384 L-ascorbic acid	yes	no	no		
300	30045	00001238045	8045 3-hydroxybutanoic acid, butyl ester	yes	no	no		
301	89120	00001238912	8912 3-hydroxybutanoic acid, butyl ester	yes	no	no		
302	12820	00001239820	9820 3-hydroxybutanoic acid	no	yes	no		
303	12130	00001240130	4013 adipic acid	yes	yes	no		
	31730							
304	14320	00001240720	4072 adipic acid	yes	yes	no		
	41960							
305	15274	00001240940	4094 hexamethylenediamine	no	no	no	2,4	
	18460							
306	88960	00001241660	4166 adipamide	no	no	no		
307	42160	00001242160	4216 carbon dioxide	yes	no	no		
308	91200	00001261360	6136 isobutyrate acetate	yes	no	no		
309	91360	00001261470	6147 isobutyrate octaacetate	yes	no	no		
310	16390	00001262370	6237 1,3-propanediol dimethyl-	no	yes	no	0,05	
	22437							
311	16480	00001265800	6580 pentacerythritol	yes	no			
	51200							

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312	21490	00001269815	acrylonitrile	yes	no	ND			
313	16650	00001274630	phenylsulphone	yes	no	3			
	51570								
314	23500	0000127991-3	pinene	no	yes	no			
315	46640	0000128236-0	tert-butyl-p-cresol	yes	no	no	3		
316	23230	0000131171	phthalic acid, diallyl ester	no	yes	no	ND		
317	48880	0000131253-3	4-methoxybenzophenone	yes	no	yes	(8)		
318	48640	0000131256-6	4-hydroxybenzophenone	yes	no	no	(8)		
319	61360	0000131257-7	4-hydroxybenzophenone	yes	no	yes	(8)		
320	37680	0000136607	benzoic acid, butyl ester	yes	no	no			
321	36080	0000137666	hexyl palmitate	yes	no	no			
322	63040	0000138121-7	lactic acid, butyl ester	yes	no	no			
323	11470	0000140885	stearic acid, ethyl ester	no	yes	no	(22)		
324	83700	0000141220	oleic acid	yes	no	yes	42		

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325	10780	000014	132-1 lactic acid, n-butyl ester	no	yes	no		(22)		
326	12763 35170	000014	1243-5 aminoethanol	yes	yes	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	
327	30140	000014	178-6 lactic acid, ethyl ester	yes	no	no				
328	65040	000014	182-0 lactic acid	yes	no	no				
329	59360	000014	262-0 lactic acid	yes	no	no				
330	19470 63280	000014	3107-7 lactic acid	yes	yes	no				
331	22480	000014	3108-8 nonanol	no	yes	no				

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332	69760	0000143618-2	2,2,4-trimethyl-1-butanol	yes	no	no			
333	22775	0000144621-7	4-oxo-2-pentanoic acid	yes	yes	no	6		
	69920								
334	17005	000015166-4	1-phenylethanimine	yes	no	no	ND		
335	68960	000030102-0	1-ethanamide	yes	no	no			
336	15095	000033448-5	decanoic acid	yes	yes	no			
	45940								
337	15820	000034549-6	2,2-difluorobenzophenone	no	yes	no	0,05		
338	71020	000037349-5	3-aminobenzoic acid	yes	no	no			
339	86160	000040951-2	silicon carbide	yes	no	no			
340	47440	000046158-5	5-oxo-2-pentanamide	no	no	no			
341	13180	000049866-8	[2,2,1]hept-3-ene	no	no	no	0,05		
	22550								
342	14260	000050244-3	ε-caprolactone	yes	no	no	(29)		
343	23770	000050413-2	propanediol	no	yes	no	0,05		
344	13810	000050516-7	butanediol formal	no	yes	no	ND		(10)
	21821								
345	35840	000050630-9	6-aminidic acid	yes	no	no			
346	10030	000051410-3	4-oxo-3-pentanoic acid	no	yes	no			
347	13050	000052844-9	4-oxo-2-pentanoic acid	no	yes	no	(21)		
	25540								
348	22350	000054463-8	4-oxo-2-pentanoic acid	yes	yes	no			
	67891								
349	25550	000055210-7	4-oxo-2-pentanoic anhydride	yes	no	no	(21)		

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350	63920	0000557	159-5 hydroxybenzoic acid	no	no				
351	21730	0000563	3345-1 methyl-1-butene	no	yes	no	ND		Only to be used in polypropylene (1)
352	16360	0000576	226-1 dimethylphenol	no	yes	no	0,05		
353	42480	0000584	0018 nicotinic acid, rubidium salt	yes	no	no	12		
354	25210	0000584	284-9 toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
355	20170	0000585	0710 methacrylic acid, tert-butyl ester	yes	no	no		(23)	
356	18820	0000592	141-6 hexene	no	yes	no	3		
357	13932	0000598	332-3 buten-2-ol	no	yes	no	ND		Only to be used as a co-monomer for the preparation of polymeric additive (1)
358	14841	0000599	464-4 cumylphenol	no	yes	no	0,05		

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359	15970 48720	000061149-4	49-4 dihydroxybenzophenone	yes	yes	no		(8)		
360	57920	000062067-7	67-7 glycerol triheptanoate	yes	no	no				
361	18700	000062911-8	11-8 hexanediol	no	yes	no	0,05			
362	14350	000063048-0	48-0 carbon monoxide	no	yes	no				
363	16450	000064610-0	10-0 dioxolane	no	yes	no	5			
364	15404	000065217-3,6	17-3,6 dianhydrosorbitol	no	yes	no	5			Only to be used as a co-monomer in poly(ethylene-co-isosorbide terephthalate)
365	11680	000068942-1c	42-1c acetic acid, isopropyl ester	no	yes	no		(22)		
366	22150	000069143-2	143-2 methyl-1-pentene	no	yes	no	0,05			
367	16697	000069323-2	323-2 dodecanedioic acid	no	yes	no				
368	93280	000069316-7	16-7 dipropionic acid, dioctadecyl ester	no	yes	no		(14)		
369	12761	000069312-2	12-2 aminododecanoic acid	no	yes	no	0,05			

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370	21460	00007609310	methacrylic anhydride	yes	no		(23)		
371	11510 11830	00008186110	acrylic acid, monoester with ethyleneglycol	no	yes	no	(22)		
372	18640	00008221060	hexamethylene diisocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	0000840266-3	1-naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05		
374	21190	00008687710	methacrylic acid, monoester with ethyleneglycol	yes	no		(23)		
375	15130	0000872105-9	decene	no	yes	no	0,05		
376	66905	0000872150-4	methylpyrrolidone	yes	no	no			
377	12786	0000919330-2	aminopropyltriethoxysilane	no	yes	no	0,05	Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the	

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										reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles.
378	21970	0000923	302-4 methylmethacrylamide	no	yes	no	0,05			
379	21940	0000924	442-5 methylolacrylamide	no	yes	no	ND			
380	11980	0000925	66-1 acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931	884-0 decane	yes	no	no	0,05			Only to be used in polymers contacting foods for which simulant A is laid down
382	19490	0000947	104-6 lactam	yes	no	no	5			
383	72160	0000948	265-2 phenylindole	yes	no	yes	15			

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384	40000	0000991284-4	bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			
385	11530	0000999a611c	acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML (1) expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).	
386	55280	0001034g011c	gallic acid, octyl ester	yes	no	no		(20)		
387	26155	0001072163-5	vinylimidazole	no	yes	no	0,05			(1)
388	25080	0001120136-1	tetradecene	no	yes	no	0,05			

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389	22360	0001141236-4	1,2,3,4-naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	0001166511-6	1,6-hexadecanoic acid, dodecyl ester	yes	no	no		(20)		
391	22932	0001187923-5	perfluoromethyl perfluorovinyl ether	yes	no	no	0,05		Only to be used in anti-stick coatings	
392	72800	0001241945-7	phosphonic acid, diphenyl 2-ethylhexyl ester	yes	no	yes	2,4			
393	37280	0001302571-9	nitrobenzene	yes	no	no				
394	41280	0001305621-0	zinc hydroxide	yes	no	no				
395	41520	0001305718-8	zinc oxide	yes	no	no				
396	64640	0001309142-8	zinc hydroxide	yes	no	no				
397	64720	0001309148-4	zinc oxide	yes	no	no				
398	35760	0001309641-1	antimony trioxide	yes	no	no	0,04		SML (6) expressed as antimony	
399	81600	0001310583-3	potassium hydroxide	yes	no	no				
400	86720	0001310571-0	zinc hydroxide	yes	no	no				
401	24475	0001313821-0	zinc sulphide	no	yes	no				

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402	96240	0001314	213-2 zinc oxide	yes	no	no			
403	96320	0001314	208-3 zinc sulphide	yes	no	no			
404	67200	0001317	331-5 zinc disulphide	yes	no	no			
405	16690	0001321	741-0 divinylbenzene	yes	no	no	ND		SML (1) expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/ m) of ethylvinylbenzene.
406	83300	0001323	312-3 propyleneglycol monostearate	yes	no	no			
407	87040	0001330	414-4 sodium tetraborate	yes	no	no		(16)	
408	82960	0001330	180-9 propyleneglycol monooleate	yes	no	no			
409	62240	0001332	137-2 zinc oxide	yes	no	no			
410	62720	0001332	181-7 zinc oxide	yes	no	no			
411	42080	0001333	816-4 carbon black	yes	no	no			Primary particles of 10 – 300 nm which are aggregated to a size of 100

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									of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.
412	45200	0001335	520ppr iodide	yes	no	no	(6)		
413	35600	0001336	2116 titanium hydroxide	yes	no	no			
414	87600	0001338	5011 stearan monolaurate	yes	no	no			
415	87840	0001338	4111 stearan monostearate	yes	no	no			
416	87680	0001338	4111 stearan monooleate	yes	no	no			
417	85680	0001343	1812 succinic acid	yes	no	no			
418	34720	0001344	4211 aluminium oxide	yes	no	no			
419	92150	0001401	1511 tartaric acids	yes	no	no			According to the JECFA specifications
420	19210	0001459	0311 phthalic acid, dimethyl ester	no	yes	no	0,05		

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421	13000	0001477153-0	benzenedimethanamine	no	yes	no	0,05			
422	38515	0001533445-5	bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05			(2)
423	22937	0001623058-0	perfluoropropyl ether	no	yes	no	0,05			
424	15070	0001647116-1	decadiene	no	yes	no	0,05			
425	10840	0001663304-1	acetic acid, tert-butyl ester	no	yes	no		(22)		
426	13510	0001675252-3	bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	no	yes	no				In compliance with Commission Regulation (EC) No 1895/2005 ^a
	13610									
427	18896	0001679451-2	(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	0001709170-5	trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no				
429	13210	0001761574-4	(4-aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	0001843108-3	tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	yes	no	yes	5			
431	61600	0001843205-6	hydroxy-4-	yes	no	yes		(8)		

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			n-octyloxybenzophenone						
432	12280	0002035	adipic anhydride	no	yes	no			
433	68320	0002082	dodecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6		
434	20410	0002082	acrylic acid, diester with 1,4-butanediol	yes	no	no	0,05		
435	14230	0002123	β-lactam, sodium salt	yes	no	no		(4)	
436	19480	0002146	lauric acid, vinyl ester	no	yes	no			
437	11245	0002156	oleic acid, dodecyl ester	no	yes	no	0,05		(2)
438	38875	0002162	2,6-diisopropylphenyl carbodiimide	yes	no	no	0,05		For indirect food contact only, behind a PET layer
439	21280	0002177	methacrylic acid, phenyl ester	yes	no	no		(23)	
440	21340	0002210	methacrylic acid,	yes	no	no		(23)	

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			propyl ester						
441	38160	00023156826	benzoic acid, propyl ester	yes	no	no			
442	13780	0002425174-8	butanediol bis(2,3-epoxypropyl)ether	no	yes	no	ND		Residual(10) content = 1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.
443	12788	0002432199-7	aminoundecanoic acid	no	yes	no	5		
444	61440	00024402224	hydroxy-5'-methylphenyl)benzotriazole	yes	no	no		(12)	
445	83440	00024660923	phosphoric acid	yes	no	no			
446	10750	00024953544	acrylic acid, benzyl ester	no	yes	no		(22)	
447	20080	00024953544	acrylic acid, benzyl ester	yes	no	no		(23)	
448	11890	00024995044	acrylic acid, n-octyl ester	no	yes	no		(22)	
449	49840	00025008816	decyl disulphide	no	yes	no	3		

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450	24430	0002561	888	Basic anhydride	no	yes	no			
451	66755	0002682	220-4	methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions
452	38885	0002725	224-6	bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	0,05		Only to be used in aqueous foods
453	26320	0002768	007	Trimethoxysilane	no	yes	no	0,05		(10)
454	12670	0002855	113-2	amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6		
455	20530	0002867	4712	methacrylic acid, 2-(dimethylamino)-ethyl ester	yes	yes	no	ND		
456	10810	0002998	008	Fic acid, sec-butyl ester	no	yes	no		(22)	
457	20140	0002998	1817	methacrylic acid, sec-butyl ester	yes	yes	no		(23)	
458	36960	0003061	754	Benamids	no	yes	no			

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459	46870	0003135318-01	tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no	no			
460	14950	0003173513	hexyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
461	22420	0003173172-6	naphthalene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
462	26170	0003195178-6	vinyl-N-methylacetamide	no	yes	no	0,02		(1)
463	25840	0003290192-4	trimethylolpropane trimethacrylate	no	yes	no	0,05		
464	61280	0003293297-8	hydroxy-4-n-hexyloxybenzophenone	yes	no	yes		(8)	
465	68040	00033337628	1,2-D-triazol-2-yl]-3-phenylcoumarin	yes	no	no			

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466	50640	0003648	818-8 dioctyltin dilaurate	yes	no	no		(10)		
467	14800	0003724	650 ferric acid	yes	yes	no	0,05			(1)
	45600									
468	71960	0003825	261 perfluorooctanoic acid, ammonium salt	no	no	no				Only to be used in repeated use articles, sintered at high temperatures
469	60480	0003864	2921 hydroxy-3,5'- di-tert- butylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896	2125 hydroxy-3'- tert- butyl-5'- methylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
471	24888	0003965	555-7 sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066	207-8 methylenebis(4- methyl-6- cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074	4012 adipic acid, divinyl ester	no	yes	no	ND		5 mg/ kg in final product,	(1)

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									Only to be used as co-monomer.	
474	43600	000408013	33-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			
475	19110	000409817	1-9-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
476	16570	000412817	1,4-bis(isocyanato)benzene	yes	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
477	46720	000413024	2,4-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8			(1)
478	60180	000419147	3-5-hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	000419625	1,4-bis(isocyanato)benzene	no	yes	no				
480	46790	000422138	2,4-di-tert-butyl-4-hydroxybenzoic acid	yes	no	no				

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			tert-butylphenyl ester								
481	13060	0004422195-5	1,3,5-benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML (1) expressed as 1,3,5-benzenetricarboxylic acid		
482	21100	00046552416	methacrylic acid, isopropyl ester	yes	no			(23)			
483	68860	000472448-5	4-octylphosphonic acid	yes	no	no	0,05				
484	13395	000476720-7	bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)	
485	13560 15700	000512430-1	4,4'-thiobis(hexamethylene)diisocyanate	yes	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)	
486	54005	000513644-7	ethyl N-palmitamide-N'-stearamide	yes	no	no					
487	45640	0005232299-5	3,3'-dicyanodiphenylacrylic acid, ethyl ester	yes	no	no	0,05				
488	53440	000551818-3	1,4-ethylenbis(palmitamide)	yes	no	no					

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489	41040	0005743	36-2m butyrate	yes	no	no			
490	16600	0005873	55-phenylmethane-2,4'-diisocyanate	no	no	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	0006182	11-2 propyleneglycol distearate	yes	no	no			
492	45650	0006197	230-4 cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	yes	no	no	0,05		
493	39200	0006200	14-2 hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	yes	no	no	1,8		
494	62140	0006303	31-5 hypophosphorous acid	no	no	no			
495	35160	0006642	2631-5 amino-1,3-dimethyluracil	yes	no	no	5		
496	71680	0006683	18-8 tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	no	no	no			
497	95020	0006846	252-4 trimethyl-1,3-pentenediol diisobutyrate	yes	no	no	5	Only to be used in single-	

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									use gloves	
498	16210	0006864337-5	dimethyl-4,4'-diaminodicyclohexylmethane	no	yes	no	0,05		Only to be used in polyamides	(5)
499	19965 65020	0006915117	maleic acid	yes	yes	no			In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis	
500	38560	0007128264-5	bis(5-tert-butyl-2-benzoxazolyl)thiophene	yes	no	yes	0,6			
501	34480	—	aluminium fibers, flakes and powders	yes	no	no				
502	22778	0007456468-0	oxybis(benzenesulphonylazide)	no	yes	no	0,05			(1)
503	46080	0007585839-9	dextrin	yes	no	no				

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504	86240	000763	silicon dioxide	yes	no	no			For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.
505	86480	000763	sulphur bisulphite	yes	no	no		(19)	
506	86920	000763	sodium nitrite	yes	no	no	0,6		
507	59990	000764	hydrochloric acid	yes	no	no			
508	86560	000764	sodium bromide	yes	no	no			
509	23170	000766	phosphoric acid	yes	yes	no			
	72640								
510	12789	000766	ammonia	yes	yes	no			
	35320								

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511	91920	0007664	45019	peroxy acid	yes	no	no			
512	81680	0007681	10108	potassium iodide	yes	no	no	(6)		
513	86800	0007681	8215	potassium iodide	yes	no	no	(6)		
514	91840	0007704	45019	peroxy acid	yes	no	no			
515	26360	0007732	21005	water	yes	yes	no			In compliance with Directive 98/83/EC ^b
	95855									
516	86960	0007757	8217	sulphite	yes	no	no	(19)		
517	81520	0007758	9023	potassium bromide	yes	no	no			
518	35845	0007771	44010	iodic acid	yes	no	no			
519	87120	0007772	9081	thiosulphate	yes	no	no	(19)		
520	65120	0007773	3001	manganese chloride	yes	no	no			
521	58320	0007782	4201	zinc white	yes	no	no			
522	14530	0007782	5101	zinc white	no	yes	no			
523	45195	0007787	7004	potassium bromide	yes	no	no			
524	24520	0008001	1021	paraffin oil	no	yes	no			
525	62640	0008001	1006	paraffin wax	yes	no	no			
526	43440	0008001	1075	paraffin	yes	no	no			
527	14411	0008001	1079	paraffin oil	yes	yes	no			
	42880									
528	63760	0008002	1041	paraffin	yes	no	no			

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529	67850	0008002537	non-an wax	yes	no	no				
530	41760	0008006448	cellulose wax	yes	no	no				
531	36880	0008012893	beeswax	yes	no	no				
532	88640	0008013078	oil, epoxidised	yes	no	no	60 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined

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540	63940	00080621505	phosphoric acid	yes	no	no	0,24		Only to be used as dispersant for plastics dispersions
541	58480	00090000115	arabic gum	yes	no	no			
542	42640	00090000117	cellulose	yes	no	no			
543	45920	00090000112	cellulose	yes	no	no			
544	58400	00090000110	gum	yes	no	no			
545	93680	00090000115	gum	yes	no	no			
546	71440	00090000115	gum	yes	no	no			
547	55440	00090000115	gum	yes	no	no			
548	42800	00090000115	gum	yes	no	no			
549	80000	00090000115	wax	yes	no	no			
550	81060	00090000115	wax	yes	no	no			
551	79920	00090000115	glycol	yes	no	no			
552	81500	00090000115	polyamide	yes	no	no			The substance shall meet the purity criteria as laid down in Commission Directive

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									2008/84/ EC ^c
553	14500	0009004e3116	cellulose	yes	yes	no			
	43280								
554	43300	0009004e3118	cellulose acetate butyrate	yes	no	no			
555	53280	0009004e571c	cellulose	yes	no	no			
556	54260	0009004e5814	hydroxyethylcellulose	yes	no	no			
557	66640	0009004e5915	ethylcellulose	yes	no	no			
558	60560	0009004e6210	hydroxyethylcellulose	yes	no	no			
559	61680	0009004e6412	propylcellulose	yes	no	no			
560	66700	0009004e6513	hydroxypropylcellulose	yes	no	no			
561	66240	0009004e6715	cellulose	yes	no	no			
562	22450	0009004e7010	cellulose	yes	yes	no			
563	78320	0009004e971e	polyethylene glycol monoricinoleate	yes	yes	no	42		
564	24540	000900552618	starch, edible	yes	yes	no			
	88800								
565	61120	0009005h3710	hydroxyethyl starch	yes	no	no			
566	33350	0009005a1217	lactic acid	yes	no	no			
567	82080	0009005137-2	propyleneglycol alginate	yes	no	no			
568	79040	0009005p0415	polyethylene glycol sorbitan monolaurate	yes	no	no			
569	79120	0009005p0516	polyethylene glycol sorbitan monooleate	yes	no	no			
570	79200	0009005p0617	polyethylene glycol sorbitan monopalmitate	yes	no	no			

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571	79280	00090056	poly(8-hydroxyoctyl) glycol sorbitan monostearate	yes	no			
572	79360	00090057	poly(3-hydroxybutyl) glycol sorbitan trioleate	yes	no			
573	79440	00090057	poly(4-hydroxybutyl) glycol sorbitan tristearate	yes	no			
574	24250	00090060	6-olefin, natural	yes	yes	no		
	84560							
575	76721	00631486	polydimethylsiloxane (Mw > 6 800 Da)	yes	no			Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)
576	60880	00090324	hydroxyethyl methylcellulose	yes	no			
577	62280	00090441	isobutylene-butene copolymer	yes	no	no		
578	79600	00090460	poly(9-tridecyl ether phosphate)	yes	no	5		For materials and articles intended for contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl

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									ether phosphate (mono- and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether.
579	61800	00090491747	hydroxypropyl starch	yes	no	no			
580	46070	001001620-3	dextrin	yes	no	no			
581	36800	001002211-8	barium nitrate	yes	no	no			
582	50240	001003933-5	octyltin bis(2-ethylhexyl maleate)	yes	no	no	(10)		
583	40400	001004311-5	boron nitride	yes	no	no	(16)		
584	13620 40320	001004311-3	boric acid	yes	yes	no	(16)		
585	41120	001004311-4	beryllium chloride	yes	no	no			
586	65280	001004311-2	barium hypophosphite	yes	no	no			
587	68400	001009445-8	butylacrylamide	yes	no	yes	5		
588	64320	001037711-2	lithium iodide	yes	no	no	(6)		
589	52645	001043608-1	eicosenamide	yes	no	no			

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590	21370	0010595	8019 acrylic acid, 2-sulphoethyl ester	yes	no	ND			(1)
591	36160	0010605	0017 stearate	no	no				
592	34690	0011097	5019 magnesium carbonate hydroxide	no	no				
593	44960	0011104	4017 oxide	yes	no	no			
594	65360	0011129	6019 oxide	no	no				
595	19510	0011132	1723 cellulose	yes	no				
596	95935	0011138	6617 gum	yes	no				
597	67120	0012001	1262 Inca	yes	no	no			
598	41600	0012004 0037293	4117 aluminum silicate	yes	no	no			
599	36840	0012007	5115 tetraborate	yes	no	no	(16)		
600	60030	0012072	9017 magnesium	no	no				
601	35440	0012124	0719 bromide	yes	no	no			
602	70240	0012198	2315 erite	yes	no	no			
603	83460	0012269	7827 phylite	yes	no	no			
604	60080	0012304	6513 talcite	yes	no	no			
605	11005	0012542	3012 acid, dicyclopentenyl ester	no	yes	no	0,05		(1)
606	65200	0012626	8819 hydroxide	no	no				
607	62245	0012751	2213 phosphide	yes	no	no			Only to be

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									used in PET polymers and copolymers
608	40800	0013003414-8	butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	yes	no	yes	6		
609	83455	0013445562	pyrophosphorous acid	no	no	no			
610	93440	0013463677	tin dioxide	yes	no	no			
611	35120	0013560349-1	aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no			
612	16694	0013811502	divinyl-2-imidazolidinone	no	yes	no	0,05		(10)
613	95905	0013983710	styrene	yes	no	no			
614	45560	0014464460	calcite	yes	no	no			
615	92080	0014807106-6	calcite	yes	no	no			
616	83470	0014808607	calcite	yes	no	no			
617	10660	0015214289-8	acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05		
618	51040	0015535479-2	octyltin mercaptoacetate	yes	no	no		(10)	

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619	50320	0015571	158-1 dioctyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)		
620	50720	0015571	160-5 dioctyltin dimaleate	yes	no	no		(10)		
621	17110	0016219	575-3 ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	0016260	009-6 N-ethylpalmitamide	no	yes	no	5			
623	52640	0016389	488-1 zinc stearate	yes	no	no				
624	18897	0016712	264-4 2-hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	0017194	400-2 zinc hydroxide	yes	no	no				
626	57800	0018641	177-1 glycerol tribehenate	yes	no	no				
627	59760	0019569	211-2 zinc stearate	yes	no	no				
628	96190	0020427	278-1 zinc hydroxide	yes	no	no				
629	34560	0021645	511-1 zinc hydroxide	yes	no	no				
630	82240	0022788	112-8 propyleneglycol dilaurate	yes	no	no				
631	59120	0023128	174-7 hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45			
632	52880	0023676	409-7 4-ethoxybenzoic acid,	yes	no	no	3,6			

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			ethyl ester						
633	53200	0023949266-8	ethoxy-2'-ethyloxanilide	yes	no	yes	30		
634	25910	002480044-0	propylene glycol			no			
635	40720	002501346-5	butyl-4-hydroxyanisole	yes	no	no	30		
636	31500	002513451-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester
637	71635	002515196-6	erythritol dioleate			no	no	0,05	Not to be used for articles in contact with fatty foods for which simulant D is laid down
638	23590	002532268-2	diethylene glycol			no			
	76960								
639	23651	002532269-4	propylene glycol			no			
	80800								
640	54930	002535990-1	formaldehyde-naphthol, copolymer			no	no	0,05	

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641	22331	0025513	6448 of (35-45 % w/w) 1,6- diamino-2,2,4- trimethylhexane and (55-65 % w/ w)1,6- diamino-2,4,4- trimethylhexane	no	yes	no	0,05		(10)
642	64990	0025736	6442c anhydride- styrene, copolymer, sodium salt	yes	no	no		The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w)	
643	87760	0026266	5759a monopalmitate	yes	no	no			
644	88080	0026266	5800a trioleate	yes	no	no			
645	67760	0026401	865- n- octyltin tris(isooctyl mercaptoacetate)	yes	no	no		(11)	
646	50480	0026401	97-8 octyltin bis(isooctyl mercaptoacetate)	yes	no	no		(10)	
647	56720	0026402	233a glycerol monohexanoate	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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648	56880	0026402	2660	glycerol mono-octanoate	yes	no	no			
649	47210	0026427	4076	di-tert-butyltin diacetate polymer	yes	no	no			Molecular unit = $(C_8H_{18}S_3Sn_2)_n$ (n = 1,5-2)
650	49600	0026636	6014	dimethylbis(isooctyl mercaptoacetate)	yes	no	no	(9)		
651	88240	0026658	8017	stearic acid tristearate	yes	no	no			
652	38820	0026741	5327	di-tert-butylphenyl pentaerythritol diphosphite	yes	no	yes	0,6		
653	25270	0026747	2900	toluene diisocyanate dimer	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
654	88600	0026836	6071	stearic acid monostearate	yes	no	no			
655	25450	0026896	4870	1,4-bis(2-chlorophenyl)propane	no	yes	no	0,05		
656	24760	0026914	4321	styrene sulphonic acid	yes	no	no	0,05		
657	67680	0027107	8017	n-octyltin tris(2-ethylhexyl mercaptoacetate)	yes	no	no		(11)	
658	52000	0027176	8740	di-tert-butylbenzenesulphonic acid	yes	no	no	30		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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659	82800	0027194172-7	propyleneglycol monolaurate	yes	no	no				
660	47540	0027458400-8	dodecyl disulphide	yes	no	yes	0,05			
661	95360	0027676162-5	tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	5			
662	25927	0027955194-8	tris(4-hydroxyphenyl)ethane	no	yes	no	0,005		Only to be used in polycarbonates	(1)
663	64150	0028290170-1	oleic acid	yes	no	no				
664	95000	0028931674-1	trimethyl propyl methacrylate-methyl methacrylate copolymer	no	no	no				
665	83120	0029013428-3	propyleneglycol monopalmitate	yes	no	no				
666	87280	0029116508-1	oleic acid	yes	no	no				
667	55190	0029204621-1	oleic acid	yes	no	no				
668	80240	0029894357-7	polyglycerol ricinoleate	no	no	no				
669	56610	0030233648-8	monobehenate	yes	no	no				
670	56800	0030899672-8	monolaurate diacetate	yes	no	no		(32)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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671	74240	0031570	04-4 phosphoric acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no			
672	76845	0031831	51-5 polyester of 1,4-butanediol with caprolactone	yes	no	no	(29) (30)	The fraction with molecular weight below 1 000 Da should not exceed 0,5 % (w/w)	
673	53670	0032509	66-6 polyethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6		
674	46480	0032647	67-0 azylidene sorbitol	yes	no	no			
675	38800	0032687	71-8 bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15		
676	50400	0033568	99-9 octyltin bis(isooctyl maleate)	yes	no	no	(10)		
677	82560	0033587	20-1 propyleneglycol dipalmitate	yes	no	no			
678	59200	0035074	76-2 hexamethylene-	yes	no	yes	6		

a [OJ L 302, 19.11.2005, p. 28.](#)

b [OJ L 330, 5.12.1998, p. 32.](#)

c [OJ L 253, 20.9.2008, p. 1.](#)

d [OJ L 226, 22.9.1995, p. 1.](#)

e [OJ L 158, 18.6.2008, p. 17.](#)

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			bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)							
679	39060	0035958430-6	bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5			
680	94400	003644366812	bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	yes	no	no	9			
681	18310	0036653482-4	hexadecanol	no	yes	no				
682	53270	003720560112	ethylcellulose	yes	yes	no				
683	66200	003720660112	ethylcellulose	no	yes	no				
684	68125	003724440616	ephaline syenite	yes	no	no				
685	85950	003729651712	acid, magnesium-sodium-fluoride salt	yes	no	no	0,15			SML expressed as fluoride. Only to be used in layers of multi-layer materials not coming into direct contact

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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										with food.
686	61390	0037353	5906	hydroxyethylcellulose	no					
687	13530	0038103	206-9	bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05		
	13614									
688	92560	0038613	6774	bis(3,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	yes	no	yes	18		
689	95280	0040601	176-5	tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	6		
690	92880	0041484	435-0	bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	no	yes	no	2,4		
691	13600	0047465	397-4	bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8		
692	52320	0052047	25043	dodecylphenylindole	yes	no	yes	0,06		
693	88160	0054140	3064	sorbitan tripalmitate	yes	yes	no			
694	21400	0054276	3516	methacrylic acid,	yes	no	no	0,05		(1)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			sulphopropyl ester						
695	67520	0054849	286 methyl tin tris(isooctyl mercaptoacetate)	no	no		(9)		
696	92205	0057569	10 phthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	no	no				
697	67515	0057583	286 methyl tin tris(ethylhexyl mercaptoacetate)	no	no		(9)		
698	49595	0057583	35 methyl tin bis(ethylhexyl mercaptoacetate)	no	no		(9)		
699	90720	0058446	29 styrene	no	no				
700	31520	0061167	58 phthalic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	yes	no	yes	6		
701	40160	0061269	6,6-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4		
702	87920	0061752	68 stearic acid tetrastearate	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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703	17170	00617884	fatty acids, coco	no	yes	no			
704	77600	00617888	polyethylene glycol ester of hydrogenated castor oil	yes	no	no			
705	10599/90 10599/91	00617888	fatty, unsaturated (C ₁₈), dimers, non hydrogenated, distilled and non-distilled	no	yes	no		(18)	(1)
706	17230	00617904	fatty acids, tall oil	no	yes	no			
707	46375	00617905	diatomaceous earth	no	no	no			
708	77520	00617911	polyethylene glycol ester of castor oil	yes	no	no	42		
709	87520	00625688	soften monobehenate	yes	no	no			
710	38700	00633976	carbutoxyethyltin-bis(isooctyl mercaptoacetate)	yes	no	yes	18		
711	42000	00634388	carbutoxyethyltin-tris(isooctyl mercaptoacetate)	yes	no	yes	30		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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712	42960	0064147	406 oil, dehydrated	yes	no	no				
713	43480	0064365	charcoal activated	yes	no	no				Only for use 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 ^d with exception of ash content which can be up to 10 % (w/w).
714	84400	0064365	179 hydrogenated, ester with pentaerythritol	yes	no	no				
715	46880	0065140	391-2 tert- butyl-4- hydroxybenzyl acid,	yes	no	no	6			

^a OJ L 302, 19.11.2005, p. 28.

^b OJ L 330, 5.12.1998, p. 32.

^c OJ L 253, 20.9.2008, p. 1.

^d OJ L 226, 22.9.1995, p. 1.

^e OJ L 158, 18.6.2008, p. 17.

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			monoethyl ester, calcium salt						
716	60800	006544717(20)	yes hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	no	no	30			
717	84210	006599706(1)	yes hydrogenated	no	no				
718	84240	006599703(9)	yes hydrogenated, ester with glycerol	no	no				
719	65920	006682216(4)	yes methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt - octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	no	no				
720	67360	006764916(4)	yes n-dodecyltin	no	no		(25)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			tris(isooctyl mercaptoacetate)						
721	46800	0067845395-6	5-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	yes	no	no			
722	17200	0068308512	faty acids, soya	no	yes	no			
723	88880	0068412523	starch, hydrolysed	yes	no	no			
724	24903	0068425173	syrups, hydrolysed starch, hydrogenated	no	yes	no			In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ^e
725	77895	0068439406	polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether	yes	no	no	0,05		The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈)

^a OJ L 302, 19.11.2005, p. 28.

^b OJ L 330, 5.12.1998, p. 32.

^c OJ L 253, 20.9.2008, p. 1.

^d OJ L 226, 22.9.1995, p. 1.

^e OJ L 158, 18.6.2008, p. 17.

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									ether (approximately 28 %), fatty alcohols (C ₁₆ -C ₁₈) (approximately 48 %), ethyleneglycol monoalkyl (C ₁₆ -C ₁₈) ether (approximately 24 %),
726	83599	0068442	2nd 26 products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes	(9)		
727	43360	0068442	28th 10 regenerated	yes	no	no			
728	75100	0068515 0028553	18th 10 diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than	yes	no	no	(26) (32)	Only to be used as: (a)	(7) plasticiser in repeated use materials and articles;

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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			60 % C ₉					(b)	plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;
								(c)	technical support
a	OJ L 302, 19.11.2005, p. 28.								
b	OJ L 330, 5.12.1998, p. 32.								
c	OJ L 253, 20.9.2008, p. 1.								
d	OJ L 226, 22.9.1995, p. 1.								
e	OJ L 158, 18.6.2008, p. 17.								

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									agent in concentrations up to 0,1 % in the final product.
729	75105	0068515 0026761	Phthalic acid diesters with primary, saturated C ₉ -C ₁₁ alcohols more than 90 % C ₁₀	yes	no	no	(26) (32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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										or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
730	66930	0068554	470-11	no	yes	no				Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane
731	18220	0068564	488-5	no	yes	no	0,05			(2)
732	45450	0068610	451-5	yes	no	yes	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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			isobutylene, copolymer						
733	10599/92	0068783	4115, fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled and non-distilled	no	yes	no		(18)	(1)
	10599/93								
734	46380	0068855	540, magnes earth, soda ash flux-calcined	yes	no	no			
735	40120	0068951	508, polyethylene glycol hydroxymethylphosphonate	yes	no	no			
736	50960	0069226	444, octyltin ethyleneglycol bis(mercaptoacetate)	yes	no	no		(10)	
737	77370	0070142	234, polyethylene glycol-30 dipolyhydroxystearate	yes	no	no			
738	60320	0070321	282, 7-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenylbenzotriazole	yes	no	yes	1,5		
739	70000	0070331	291, oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no			
740	81200	0071878	1086, [(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-(2,2,6,6-	yes	no	yes	3		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			tetramethyl-4-piperidyl-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl imino]							
741	24070 83610	0073138-83610	acids and rosin acids	yes	yes	no				
742	92700	0078301242,64	tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5			
743	38950	00790725964	ethylbenzylidene)sorbitol	yes	no	no				
744	18888	0080181331-3	hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no				The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I
745	68145	0080410232,9'	nitrilo(triethyl	yes	no	yes	5			SML expressed

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite)						as sum of phosphite and phosphate
746	38810	008069350026	di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
747	47600	0084030615	dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)	
748	12765	0084434128	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05		
749	66360	0085209221	2-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5		
750	66350	0085209224	4-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5		
751	81515	0087189225	2,5-bis(zinc glycerolate)	yes	no	no			
752	39890	008782641-30069158-41	4-(methylbenzylidene)sorbitol	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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		40054686-97 — 40081541-12-0							
753	62800	00927044011, calcined kaolin	yes	no	no				
754	56020	00998806465 dibhenate	yes	no	no				
755	21765	0106246434-7 methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05			(1)
756	40020	0110553224-0 bis(octylthiomethyl)-6-methylphenol	yes	no	yes			(24)	
757	95725	01106387216-6 zinc carbonate reaction product with citric acid, lithium salt	yes	no	no				
758	38940	0110675224-8 bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes			(24)	
759	54300	0118337209-0 ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6			
760	83595	01193451501-0 reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-	yes	no	no	18			Composition: — 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl					—	w (*), 4,3'- biphenylene- bis[0,0- bis(2,4- di- tert- butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/ w (*), 3,3'- biphenylene- bis[0,0- bis(2,4- di- tert- butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/ w (*), 4- biphenylene-0,0- bis(2,4- di- tert- butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/ w (*), tris(2,4- di- tert- butylphenyl)phosphite (CAS No 0031570-04-4)
a	OJ L 302, 19.11.2005, p. 28.								
b	OJ L 330, 5.12.1998, p. 32.								
c	OJ L 253, 20.9.2008, p. 1.								
d	OJ L 226, 22.9.1995, p. 1.								
e	OJ L 158, 18.6.2008, p. 17.								

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									(9-18 % w/ w (*)), 4,4'- biphenylene-0,0- bis(2,4- di- tert- butylphenyl)phosphonate-0- bis(2,4- di- tert- butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/ w (*))
								(*)	Quantity of substance used/ quantity of formulation
								Other specifications: —	Phosphor content of min. 5,4 % to max. 5,9 %, Acid value of max. 10 mg KOH per gram,
a	OJ L 302, 19.11.2005, p. 28.								
b	OJ L 330, 5.12.1998, p. 32.								
c	OJ L 253, 20.9.2008, p. 1.								
d	OJ L 226, 22.9.1995, p. 1.								
e	OJ L 158, 18.6.2008, p. 17.								

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										Melt range of 85–110 °C,
761	92930	0120218	Bis[4-(methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)]	no	no	yes	6			
762	31530	0123968	2,5-Di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester	yes	no	yes	5			
763	39925	0129228	2,3-bis(methoxymethyl)-2,5-dimethylhexane	yes	no	yes	0,05			
764	13317	0132459	4,4'-bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide	no	yes	no	0,05		Purity > 98,1 % (w/w). Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT).	
765	49485	0134701	2,6-dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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766	38879	013586156-24	bis(2,4-dimethylbenzylidene)sorbitol	yes	no	no			
767	38510	013650419-6	bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	yes	no	no	5		
768	34850	014392590-2	bis(hydrogenated tallow alkyl) oxidised amines	yes	no	no		Not to be used for articles in contact with fatty foods for which simulant D is laid down. Only to be used in:	(1)
								(a)	polyolefins at 0,1 % (w/w) concentration and in PET at
								(b)	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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										0,25 % (w/ w) concentration.
769	74010	0145650	Phosphoric acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	yes	no	yes	5			SML expressed as sum of phosphite and phosphate
770	51700	0147315	2,4-bis(4,5-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05			
771	34650	0151841	6-hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5			
772	47500	0153250	2,3-dicyclohexyl-2,6-naphthalene dicarboxamide	yes	no	no	5			
773	38840	0154862	2,4-bis(2,4-dicumylphenyl) diposphite	yes	no	yes	5			SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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									(2,4-dicumylphenol)
774	95270	016171723264	2,2,4,4-tetrakis(tert-butylphenyl)-2-butyl-2-ethyl-1,3-propanediol phosphite	yes	no	yes	2		SML expressed as sum of phosphite, phosphate and the hydrolysis product = TTBP
775	45705	0166412178	8-cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)	
776	76723	0167883051	3-(3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate) dimethylsiloxane,	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 1,5 % (w/w)
777	31542	0174254251	2,2,4,4-tetrakis(alkyl acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters)	yes	no	no			0,5 % (1) in final product

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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778	71670	0178671	1584	polyethylene tetrakis (2-cyano-3,3-diphenylacrylate)	no	yes	0,05			
779	39815	0182121	1912-6	bis(methoxymethyl)fluorene	yes	yes	0,05			(1)
780	81220	0192268	647	[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	yes	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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781	95265	0227099160-57	1,3,5-tris(4-benzoylphenyl)benzene	yes	no	no	0,05			
782	76725	06614760-1	polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane			no				The fraction with molecular weight below 1 000 Da should not exceed 1 % (w/w)
783	55910	07361506-3	polyester castor-oil mono-, hydrogenated, acetates	yes	no	no		(32)		
784	95420	0745070161-5	1,3,5-tris(2,2-dimethylpropanamido)benzene	yes	no	no	0,05			
785	24910	00001000-1	terephthalic acid	yes	no			(28)		
786	14627	0000117321-5	3-chlorophthalic anhydride	no	yes	no	0,05			SML expressed as 3-chlorophthalic acid
787	14628	0000118445-6	4-chlorophthalic anhydride	no	yes	no	0,05			SML expressed as 4-chlorophthalic acid
788	21498	0002530135-0	[3-(methacryloxy)propyl]trimethoxysilane	no	yes	no	0,05			Only to be used (1) (11)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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									as a surface treatment agent of inorganic fillers
789	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)	yes	no	no			Average (2) molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10 ⁻⁶ m ² /s).
790	80480	009075 008245	poly(1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	yes	no	no	5		Average (16) molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/kg, of N,N'-

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

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									bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg.
791	92470	0106990	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	yes	no	no	0,05		
792	92475	0203255	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid	yes	no	yes	5		SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products
793	94000	0000102	7-ethanoylamine	yes	no	no	0,05		SML expressed as the sum of

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									triethanolamine and the hydrochloride adduct expressed as triethanolamine	
794	18117	0000079	glycolic acid	no	yes	no			For indirect food contact only, behind a PET layer	
795	40155	0124172	N,N-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine	yes	no	no	0,05		(2) (12)	
796	72141	0018602	(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	yes	no	yes	0,05		SML including the sum of its hydrolysis products	
797	76807	0007328	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		
798	92200	0006422	terephthalic acid,	yes	no	no	60	(32)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			bis(2-ethylhexyl)ester							
799	77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8			In compliance with the purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1)
800	94425	0000867	triethyl phosphonoacetate	yes	no	no				Only for use in PET
801	30607	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, from natural oils	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			and fats, lithium salt						
802	33105	0146340	alcohols C ₁₂ - C ₁₄ secondary, β-(2- hydroxyethoxy), ethoxylated	yes	no	no	5		(12)
803	33535	0152261	33-1 alkenes (C ₂₀ - C ₂₄) copolymer with maleic anhydride, reaction product with 4- amino-2,2,6,6- tetramethylpiperidine	yes	no	no		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.	(13)
804	80510	1010121	8073- nonyl-1,1- dioxo-1- thiopropene-1,3- diyl)- block- poly(x- oleyl-7- hydroxy-1,5- diiminoctane-1,8-	yes	no	no		Only to be used as polymer production aid in polyethylene (PE), polypropylene	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid						(PP) and polystyrene (PS)
805	93450	—	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	yes	no	no			The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w
806	14876	0001076197-7	cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters
807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles. Only to be used in PET bottles up to

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									20 mg/kg. In the PET, the agglomerates have a diameter of 100 – 500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.
808	38550	0882073b14	14(4) propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products
809	49080	0852282N89-4	(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione	yes	no	yes	0,05		Only (6) for use (14) in PET (15)
810	68119		neopentyl glycol, diesters and monoesters with	yes	no	no	5	(32)	Not to be used for articles in

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			benzoic acid and 2-ethylhexanoic acid						contact with fatty foods for which simulant D is laid down.
811	80077	006844	polyethylene waxes, oxidised	no	no	60			
812	80350	0124578	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	no	no				Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
813	91530	—	sulphosuccinic acid alkyl (C ₄ -	no	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			C ₂₀) or cyclohexyl diesters, salts						
814	91815	—	sulphosulphonic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts	yes	no	no	2		
815	94985	—	trimethylpropyl mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid	no	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which simulant D is laid down
816	45704	—	cis-1,2-cyclohexanedicarboxylic acid, salts	yes	no	no	5		
817	38507	—	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	yes	no	no	5		Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %.

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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818	21530	—	methallyl sulphonic acid, salts	yes	no	no	5			
819	68110	—	neodecanoic acid, salts	yes	no	no	0,05		Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D is laid down. SML expressed as neodecanoic acid.	
820	76420	—	pimelic acid, salts	yes	no	no				
821	90810	—	stearoyl-lactylic acid, salts	yes	no	no				
822	71938	—	perchloric acid, salts	yes	no	no	0,05			(4)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5			
854	71943	0329238	perfluoroacetic acid, α -substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups	yes	no	no				Only to be used in concentrations up to 0,5 % w/w in the polymerisation of fluoropolymers that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles
860	71980	0051798	perfluoro[2-(poly(n-propoxy))propanoic acid]	yes	no	no				Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									above 265 °C and are intended for use in repeated use articles
861	71990	0013252	2p1336 (n-propoxy)propanoic acid]	no	no				Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
862	15180	0018085	302-4 diacetoxy-1-butene	no	yes	no	0,05		SML including the hydrolysis product 3,4-dihydroxy-1-butene. Only for use as a co-

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									monomer for ethyl vinyl alcohol copolymers.
864	46330	0000056206-4	206-4 diamino-6-hydroxypyrimidine	yes	no	no	5		Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic aqueous food
865	40619	0025322(00-01	00-01 acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 1 %
866	40620	—	(butyl acrylate, methyl methacrylate) copolymer, cross-linked with	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			allyl methacrylate						maximum level of 7 %
867	40815	0040471	(00-21) yes methacrylate, ethyl acrylate, methyl methacrylate) copolymer	no	no				Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %
868	53245	0009010	(00-21) yes acrylate, methyl methacrylate) copolymer	no	no				Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %
869	66763	0027136	(00-21) yes acrylate, methyl methacrylate, styrene) copolymer	no	no				Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 %
870	95500	0160535	N,N'-tris(2-methylcyclohexyl)-1,2,3-	yes	no	no	5		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			propane- tricarboxamide						
875	80345	0058128	poly(12-hydroxystearic acid) stearate	yes	no	yes	5		
878	31335	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C ₃ -C ₂₂)	yes	no	no			
879	31336	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric,	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

			saturated, primary (C ₁ -C ₂₂)						
880	31348	0085116	0034, fatty (C ₈ -C ₂₂), esters with pentaerythritol	yes	no	no			
881	25187	0003010	296,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for repeated use articles for long term storage at room temperature or below and hotfill
882	25872	0002416	293,6-trimethylphenol	no	yes	no	0,05		
883	22074	0004457	371-0-methyl-1,5-pentandiol	no	yes	no	0,05		Only to be used in materials in contact with food at a surface to mass ratio up to

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

									0,5 dm ² / kg	
884	34240	0091082	alkyl(C ₁₀ -C ₂₁)sulphonic acid, esters with phenol	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down.	
885	45676	0263244	oligomers of (butylene terephthalate)	yes	no	no			Only to be used in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and rigid poly(vinyl chloride) (PVC) plastics in concentrations up to 1 % w/w, in contact	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

											with aqueous, acidic and alcoholic foods, for long term storage at room temperature.
a	OJ L 302, 19.11.2005, p. 28.										
b	OJ L 330, 5.12.1998, p. 32.										
c	OJ L 253, 20.9.2008, p. 1.										
d	OJ L 226, 22.9.1995, p. 1.										
e	OJ L 158, 18.6.2008, p. 17.										

2. Group restriction of substances

Table 2 on Group restrictions contains the following information:

Column 1 (Group restriction No): contains the identification number of the group of substances for which the group restriction applies. It is the number referred to in Column 9 in Table 1 of this Annex.

Column 2 (FCM substance No): contains the unique identification numbers of the substances for which the group restriction applies. It is the number referred to in Column 1 in Table 1 of this Annex.

Column 3 (SML (T) [mg/kg]): contains the total specific migration limit for the sum of substances applicable to this group. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 4 (Group restriction specification): contains an indication of the substance whose molecular weight forms the basis for expression of the result.

TABLE 2

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T)[mg/kg]	Group restriction specification
1	128 211	6	expressed as acetaldehyde
2	89 227 263	30	expressed as ethyleneglycol
3	234 248	30	expressed as maleic acid

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

4	212 435	15	expressed as caprolactam
5	137 472	3	expressed as the sum of the substances
6	412 512 513 588	1	expressed as iodine
7	19 20	1,2	expressed as tertiary amine
8	317 318 319 359 431 464	6	expressed as the sum of the substances
9	650 695 697 698 726	0,18	expressed as tin
10	28 29 30 31 32 33 466 582 618 619 620 646 676 736	0,006	expressed as tin
11	66 645 657	1,2	expressed as tin
12	444 469 470	30	expressed as the sum of the substances
13	163 285	1,5	expressed as the sum of the substances
14	294 368	5	expressed as the sum of the substances

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

15	98 196	15	expressed as formaldehyde
16	407 583 584 599	6	expressed as boron Without prejudice to the provisions of Directive 98/83/EC
17	4 167 169 198 274 354 372 460 461 475 476 485 490 653	ND	expressed as isocyanate moiety
18	705 733	0,05	expressed as the sum of the substances
19	505 516 519	10	expressed as SO ₂
20	290 386 390	30	expressed as the sum of the substances
21	347 349	5	expressed as trimellitic acid
22	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	expressed as acrylic acid
23	150 156 181 183	6	expressed as methacrylic acid

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	184 355 370 374 439 440 447 457 482		
24	756 758	5	expressed as the sum of the substances
25	720 747	0,05	sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctylmercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
26	728 729	9	expressed as the sum of the substances
27	188 291	5	expressed as isophthalic acid
28	191 192 785	7,5	expressed as terephthalic acid
29	342 672	0,05	expressed as the sum of 6-hydroxyhexanoic acid and caprolactone
30	254 672	5	expressed as 1,4-butanediol
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532	60	expressed as the sum of the substances

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

670
728
729
775
783
797
798
810
815

3. Notes on verification of compliance

Table 3 on notes on verification of compliance contains the following information:

Column 1 (Note No): contains the identification number of the Note. It is the number referred to in Column 11 in Table 1 of this Annex.

Column 2 (Notes on verification of compliance): contains rules that shall be respected when testing for compliance of the substance with specific migration limits or other restrictions or it contains remarks on situations where there is a risk of non-compliance.

TABLE 3

(1) Note No	(2) Notes on verification of compliance
(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004.
(4)	Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.
(5)	Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D2 (unstable).
(6)	Migration limit might be exceeded at very high temperature.
(7)	If testing in food is performed, Annex V 1.4 shall be taken into account.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

(8)	Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm ² .
(9)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm ² /kg.
(10)	Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.
(11)	Only a method of analysis for the determination of the residual monomer in the treated filler is available.
(12)	There is a risk that the SML could be exceeded from polyolefins.
(13)	Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.
(14)	There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.
(15)	There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.
(16)	There is a risk that 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
(17)	Only a method for determination of the residual content of the substance in the polymer is available

4. Detailed specification on substances

Table 4 on detailed specifications on substances contains the following information

Column 1 (FCM substance No): contains the unique identification number of the substances referred to in Column 1 in Table 1 of Annex I to which the specification applies.

Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

(1)	(2)
-----	-----

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

FCM substance No	Detailed specification on the substance	
744	Definition	<p>The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications</p>
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	0080181-31-3
	Structural formula	$\begin{array}{ccccccc} & & \text{CH}_3 & & & & \\ & & & & & & \\ \text{CH}_3 & \text{O} & & \text{CH}_2 & \text{O} & & \\ & & & & & & \\ \text{-(O-CH}_2\text{)-C(=O)-} & \text{-(O-CH}_2\text{)-C(=O)-} & & \text{-(O-CH}_2\text{)-C(=O)-} & \text{-(O-CH}_2\text{)-C(=O)-} & & \end{array}$ <p>where n/(m + n) greater than 0 and less or equal to 0,25</p>

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay	Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydroxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids
	Description	White to off-white powder after isolation
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	Restriction	QMA for crotonic acid is 0,05 mg/6 dm ²
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— nitrogen,	Not more than 2 500 mg/kg of plastic
	— zinc,	Not more than 100 mg/kg of plastic
	— copper,	Not more than 5 mg/kg of plastic
	— lead,	Not more than 2 mg/kg of plastic
	— arsenic,	Not more than 1 mg/kg of plastic
	— chromium,	Not more than 1 mg/kg of plastic

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

ANNEX II

Restrictions on materials and articles

1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Barium = 1 mg/kg food or food simulant.

Cobalt = 0,05 mg/kg food or food simulant.

Copper = 5 mg/kg food or food simulant.

Iron = 48 mg/kg food or food simulant.

Lithium = 0,6 mg/kg food or food simulant.

Manganese = 0,6 mg/kg food or food simulant.

Zinc = 25 mg/kg food or food simulant.

2. Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex I, in a detectable quantity into food or food simulant. The detection limit is 0,01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.

ANNEX III

Food simulants

1. Food simulants

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table 1 below are assigned.

TABLE 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A

a This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Vegetable oil ^a	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

a This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

2. General assignment of food simulants to foods

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according Table 2 below.

For testing overall migration from materials and articles intended to come into contact with different food categories or a combination of food categories the food simulant assignment in point 4 is applicable.

Table 2 contains the following information:

Column 1 (Reference number): contains the reference number of the food category.

Column 2 (Description of food): contains a description of the foods covered by the food category

Column 3 (Food simulants): contains sub-columns for each of the food simulants

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 the cross is followed by an oblique stroke and a figure, the migration test result shall be divided by this figure before comparing the result with the migration limit. The figure is the correction factor referred to in point 4.2 of Annex V to this Regulation.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4.5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic food contact material.

TABLE 2

food category specific assignment of food simulants

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
01	Beverages						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars,		X(*)	X			

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract						
	B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate		X(*)		X		
01.02	Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

01.04	Miscellaneous: undenaturated ethyl alcohol	X(*)				Substitute 95 % ethanol	
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X
02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X
02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry:						
	A. With fatty substances on					X/3	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

		the surface					
	B.	Other					X
02.06		Pastry, cakes, bread, dough and other bakers' wares, fresh:					
	A.	With fatty substances on the surface				X/3	
	B.	Other					X
03		Chocolate, sugar and products thereof Confectionery products					
03.01		Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/3	
03.02		Confectionery products:					
	A.	In solid form:					
	I.	With fatty substances on				X/3	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

		the surface					
	II.	Other					X
	B.	In paste form:					
	I.	With fatty substances on the surface				X/2	
	II.	Moist		X			
03.03		Sugar and sugar products					
	A.	In solid form: crystal or powder					X
	B.	X Molasses, sugar syrups, honey and the like					
04		Fruit, vegetables and products thereof					
04.01		Whole fruit, fresh or chilled, unpeeled					
04.02		Processed fruit:					

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	A.	Dried or dehydrated fruits, whole, sliced, flour or powder					X
	B.	Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)	X(*)	X			
	C.	Fruit preserved in a liquid medium:					
	I.	In an oily medium				X	
	II.	In an alcoholic medium			X		
04.03	Nuts (peanuts,						

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):						
	A. Shelled, dried, flaked or powdered						X
	B. Shelled and roasted						X
	C. X In paste or cream form					X	
04.04	Whole vegetables, fresh or chilled, unpeeled						
04.05	Processed vegetables:						
	A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder						X
	B. X Fresh vegetables, peeled						

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	or cut					
	C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine)	X(*)	X			
	D. Preserved vegetables:					
	I. X In an oily medium				X	
	II. In an alcoholic medium			X		
05	Fats and oils					
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				X	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

05.02	Margarine, butter and other fats and oils made from water emulsions in oil					X/2	
06	Animal products and eggs						
06.01	Fish:						
	A.	X Fresh, chilled, processed, salted or smoked including fish eggs				X/3(**)	
	B.	Preserved fish:					
	I.	X In an oily medium				X	
	II.	In an aqueous medium	X(*)	X			
06.02	Crustaceans and molluscs (including oysters, mussels, snails)						
	A.	Fresh within the shell					

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	B.	Shell removed, processed, preserved or cooked with the shell					
	I.	X In an oily medium				X	
	II.	In an aqueous medium	X(*)	X			
06.03		Meat of all zoological species (including poultry and game):					
	A.	X Fresh, chilled, salted, smoked				X/4(**)	
	B.	X Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams				X/4(**)	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	C.	X. Marinated meat products in an oily medium				X	
06.04	Preserved meat:						
	A.	X In an fatty or oily medium				X/3	
	B.	In an aqueous medium	X(*)		X		
06.05	Whole eggs, egg yolk, egg white						
	A.	Powdered or dried or frozen					X
	B.	Liquid and cooked			X		
07	Milk products						
07.01	Milk						
	A.	Milk and milk based drinks whole, partly dried and skimmed			X		

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

		or partly skimmed					
	B.	Milk powder including infant formula (based on whole milk powder)					X
07.02		Fermented milk such as yoghurt, buttermilk and similar products	X(*)		X		
07.03		Cream and sour cream	X(*)		X		
07.04		Cheeses:					
	A.	Whole, with not edible rind					X
	B.	Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese				X/3(**)	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	C.	Processed cheese (soft cheese, cottage cheese and similar)	X(*)		X		
	D.	Preserved cheese:					
	I.	X In an oily medium				X	
	II.	In an aqueous medium (feta, mozzarella, and similar)	X(*)		X		
08	Miscellaneous products						
08.01	Vinegar		X				
08.02	Fried or roasted foods:						
	A.	X Fried potatoes, fritters and the like				X/5	
	B.	X Of animal origin				X/4	
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts,						

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

	concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents					
	A. Powdered or dried:					
	I. With fatty character				X/5	
	II. Other					X
	B. any other form than powdered or dried:					
	I. X With fatty character	X(*)			X/3	
	II. Other	X(*)	X			
08.04	Sauces:					
	A. With aqueous character	X(*)	X			
	B. X With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad	X(*)			X	

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

		creams and other oil/ water mixtures e.g. coconut based sauces					
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A.	X With fatty substances on the surface				X/5	
	B.	Other					X
08.07	Ice- creams			X			
08.08	Dried foods:						
	A.	With fatty substances on the surface				X/5	
	B.	Other					X

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

08.09	Frozen or deep-frozen foods						X
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.		X(*)			X	
08.11	Cocoa:						
	A. Cocoa powder, including fat-reduced and highly fat reduced						X
	B. Cocoa paste					X/3	
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered						X
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom						X

Status: Point in time view as at 14/01/2011.

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	and others						
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other						X
08.15	Spices and seasoning in oily medium such as pesto, curry paste					X	

4. Food simulant assignment for testing overall migration

To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all types of food except for acidic foods testing in distilled water or water of equivalent quality or food simulant A and food simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and alcoholic foods and milk products testing in food simulant D1 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous, acidic and alcoholic foods and milk products testing in food simulant D1 and food simulant B shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C and food simulant B shall be performed.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

ANNEX IV

Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

- (1) the identity and address of the business operator issuing the declaration of compliance;
- (2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
- (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- (4) the date of the declaration;
- (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;
- (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;
- (7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
- (8) specifications on the use of the material or article, such as:
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
- (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

ANNEX V

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

1.1. Sample preparation

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

1.2. Conditions of testing

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. Analysis of migrated substances

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

1.4. Special cases

When contamination occurs from sources other than food contact materials this has to be taken into account when testing for compliance of the food contact materials, in particular for phthalates (FCM substance 157, 159, 283, 728, 729) referred to in Annex I.

CHAPTER 2

Testing for specific migration of materials and articles not yet in contact with food

2.1. Verification method

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7.

2.1.1. Sample preparation

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

2.1.2. Choice of food simulant

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex III.

2.1.3. Conditions of contact when using food simulants

The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

TABLE 1

Contact time	
Contact time in worst foreseeable use	Test time
$t \leq 5$ min	5 min
$5 \text{ min} < t \leq 0,5$ hour	0,5 hour
$0,5 \text{ hours} < t \leq 1$ hour	1 hour
$1 \text{ hour} < t \leq 2$ hours	2 hours
$2 \text{ hours} < t \leq 6$ hours	6 hours
$6 \text{ hours} < t \leq 24$ hours	24 hours
$1 \text{ day} < t \leq 3$ days	3 days
$3 \text{ days} < t \leq 30$ days	10 days
Above 30 days	See specific conditions

TABLE 2

Contact temperature	
Conditions of contact in worst foreseeable use	Test conditions
Contact temperature	Test temperature
$T \leq 5$ °C	5 °C
5 °C < $T \leq 20$ °C	20 °C
20 °C < $T \leq 40$ °C	40 °C
40 °C < $T \leq 70$ °C	70 °C

- a** This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C ^a
121 °C < T ≤ 130 °C	130 °C ^a
130 °C < T ≤ 150 °C	150 °C ^a
150 °C < T < 175 °C	175 °C ^a
T > 175 °C	Adjust the temperature to the real temperature at the interface with the food ^a

a This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

2.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days at room temperature and below the specimen shall be tested in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C. Testing time and temperature conditions shall be based on the following formula.

$$t_2 = t_1 * \text{Exp}((-E_a/R) * (1/T_1 - 1/T_2))$$

E_a is the worst case activation energy 80kJ/mol

R is a factor 8,31 J/Kelvin/mol

$$\text{Exp} -9627 * (1/T_1 - 1/T_2)$$

t₁ is the contact time

t₂ is the testing time

T₁ is the contact temperature in Kelvin. For room temperature storage this is set at 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °C).

T₂ is the testing temperature in Kelvin.

Testing for 10 days at 20 °C shall cover all storage times at frozen condition.

Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Testing for 10 days at 50 °C shall cover all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes and storage times of up to 6 months at room temperature.

Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

The maximum testing temperature is governed by the phase transition temperature of the polymer. At the test temperature the test specimen should not undergo any physical changes.

For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

2.1.5. Specific conditions for combinations of contact times and temperature

If a material or article is intended for different applications covering different combinations of contact time and temperature the testing should be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2.1.6. Repeated use articles

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

The material or article shall respect the specific migration limit already in the first test for substances for which in Annex I Table 1 column 8 or Table 2 column 3 the specific migration limit is set as non-detectable and for non-listed substances used behind a plastic functional barrier covered by the rules of point (b) of Articles 13(2) which should not migrate in detectable amounts.

2.1.7. Analysis of migrating substances

At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

2.1.8. Verification of compliance by residual content per food contact surface area (QMA)

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex I that verification of compliance shall be undertaken by verification of residual content per 6 dm² of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm² per kg food.

2.2. Screening approaches

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in section 2.1.

2.2.1. Replacing specific migration by overall migration

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

2.2.2. Residual content

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To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.

2.2.3. Migration modelling

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.

2.2.4. Food simulant substitutes

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants overestimate migration compared to the regulated food simulants.

CHAPTER 3

Testing for overall migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

3.1. Standardised testing conditions

The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table 3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III.

If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

TABLE 3

Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM3	2 h at 70 °C	Any contact conditions that include heating up

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		to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM4	1 h at 100 °C	High temperature applications for all food simulants at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM1 and OM3.

3.2. Substitute test for OM7 with food simulant D2

In case it is technically NOT feasible to perform OM7 with food simulant D2 the test can be replaced by test OM 8 or OM9. Both test conditions described under the respective test shall be performed with a new test sample.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
OM 8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5, and OM6
OM 9	Food simulant E for 2 hours at 175 °C and	High temperature applications	OM1, OM2, OM3, OM4, OM5 and OM6

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	food simulant D2 for 10 days at 40 °C	including long term storage at room temperature	
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3.3. Repeated use articles

Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion.

Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the overall migration limit is not exceeded on the first test, no further test is necessary.

3.4. Screening approaches

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in sections 3.1. and 3.2.

3.4.1. Residual content

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article.

3.4.2. Food simulant substitutes

To screen for overall migration food simulants can be replaced if based on scientific evidence the substitute food simulants overestimate migration compared to the regulated food simulants.

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

4.1. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF)

For lipophilic substances for which in Annex I it is indicated in column 7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula $FRF = (g \text{ fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$.

The FRF shall be applied according to the following rules.

The migration test results shall be divided by the FRF before comparing with the migration limits.

The correction by the FRF is not applicable in the following cases:

- (a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;
- (b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due

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to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

4.2. Correction of migration into food simulant D2

For the food categories where in sub-column D2 of column 3 of Table 2 of Annex III the cross is followed by a figure the migration test result into food simulant D2 shall be divided by this figure.

The migration test results shall be divided by the correction factor before comparing with the migration limits.

The correction is not applicable to the specific migration for substances in the Union list in Annex I for which the specific migration limit in column 8 is 'not detectable' and for non-listed substances used behind a plastic functional barrier covered by the rules of Article 13(2) (b) which should not migrate in detectable amounts.

4.3. Combination of correction factors 4.1 and 4.2.

The correction factors described in 4.1 and 4.2 can be combined for migration of substances for which the FRF is applicable when testing is performed in food simulant D2 by multiplying both factors. The applied maximum factor shall not exceed 5.

ANNEX VI

Correlation tables

Directive 2002/72/EC	This Regulation
Article 1(1)	Article 1
Article 1(2), (3) and (4)	Article 2
Article 1a	Article 3
Article 3(1), Article 4(1) and Article 5	Article 5
Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3)	Article 6
Article 4a(3) and (6)	Article 7
Annex II (4) and Annex III (4)	Article 8
Article 3(1) and Article 4(1)	Article 9
Article 6	Article 10
Article 5a(1) and Annex I (8)	Article 11
Article 2	Article 12
Article 7a	Article 13
Article 9(1) and (2)	Article 15

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Article 9(3)	Article 16
Article 7 and Annex I (5a)	Article 17
Article 8	Article 18
Annex II (3) and Annex III (3)	Article 19
Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI	Annex I
Annex II (2), Annex III (2) and Annex V, Part A	Annex II
Article 8(5) and Annex VIa	Annex IV
Annex I	Annex V
Directive 93/8/EEC	This Regulation
Article 1	Article 11
Article 1	Article 12
Article 1	Article 18
Annex	Annex III
Annex	Annex V
Directive 97/48/EC	This Regulation
Annex	Annex III
Annex	Annex V

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