
Status: Point in time view as at 14/09/2016.

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Status: Point in time view as at 14/09/2016.

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).

[^{F1}Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND ('not-detectable') if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).]

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

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.

Status: Point in time view as at 14/09/2016.

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

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.

[^{F2}.....]

Textual Amendments

F2 Deleted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

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] (Group No)	SML (T) [mg/kg] (Group restriction No)	Restrictions and specifications	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,	no	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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

			linear, primary (C ₄ -C ₂₂)							
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)
5	25360	—	trialkyl (C ₈ -C ₁₅) acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxy group. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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7	30370	—	acetylated acid, salts	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	no	no		(32)		
9	30610	—	acids, C ₂ - C ₂₄ , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	yes	no	no			
10	30612	—	acids, C ₂ -	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			C ₂₄ , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters							
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, saturated, linear, primary (C ₄ - C ₂₄)	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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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				

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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19	39090	—	N,N-bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine	yes	no	no		(7)		
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	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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			2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(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)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1](#).]

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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)		
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				

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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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 acetic acid	yes	no	no				
41	56486	—	glycerol esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C ₁₄ -C ₁₈) and 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C ₁₆ - C ₁₈)						
42	56487	—	glycerol esters with butyric acid	yes	no	no			
43	56490	—	glycerol esters with erucic acid	yes	no	no			
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	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			linoleic acid						
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			
52	56580	—	glycerol esters with ricinoleic acid	yes	no	no			
53	56585	—	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			stearic acid						
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, ester 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			citric acid						
60	58300	—	glycine, salts	yes	no	no			
62	64500	—	lysine, salts	yes	no	no			
63	65440	—	manganese pyrophosphite	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 %).

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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66	67600	—	mono- n- octyltin tris(alkyl(C ₁₀ - C ₁₆) mercaptoacetate)	yes	no	no		(11)		
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			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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70	76463	—	polyacrylic acid, salts	no	no		(22)		
71	76730	—	polydimethylsiloxane, γ -hydroxypropylated	no	no	6			
72	76815	—	polyesters of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C ₁₂ -C ₂₂ fatty acids	no	no		(32)	The fraction with molecular weight below 1 000 Da [F ¹ shall] 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	no	yes		(31) (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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F⁵[OJ L 83, 22.3.2012, p. 1.](#)]

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			be end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol						
74	77440	—	polyethylene glycol diricinoleate	yes	no	yes	42		
75	77702	—	polyethylene glycol esters of aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates	yes	no	no			
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether	yes	no	no	0,05		Only for use in PET

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate						
77	77733	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	no	0,05			Only for use in PET	
78	77897	—	polyethylene glycol monoalkylether (linear and branched, C ₈ -C ₂₀) sulphate, salts	no	5				
79	80640	—	polyoxyalkyl dimethylpolysiloxane	no	no				
80	81760	—	powdersy flakes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

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h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron						
81	83320	—	propylhydroxyethylcellulose						
82	83325	—	propylhydroxyethylcellulose						
83	83330	—	propylhydroxypropylcellulose						
84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no			
85	85610	—	silicates, natural, silanated (with the exception of asbestos)	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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86	86000	—	silicic acid, silylated	yes	no	no				
[^{F1} 87	86285		Silicon dioxide, silanated	yes	no	no			For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 µm and may form agglomerates within the size distribution of 0,3 µm to the mm size.]
88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no		(2)		
90	92195	—	taurine, salts	yes	no	no				
91	92320	—	tetradecyl polyethyleneglycol ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclohexane dimethanol 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 [F1 simulant D1 and/ or D2] is laid down. Average molecular weight

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 [F3 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [F4 Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5 [OJ L 83, 22.3.2012, p. 1.](#)]

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									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 less
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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									than 11 cSt (11×10^{-6} m^2/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

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									mineral hydrocarbons with Carbon number 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

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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									of cracked petroleum stocks with a boiling range not greater than 220 °C, 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: >
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
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h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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									95 °C as determined by ASTM Method E 28-67, Bromine number: < 40 (ASTM D1159), The colour of a 50 % solution in toluene < 11 on the Gardner scale, Residual aromatic monomer ≤ 50 ppm,
98	17260	0000050	Formaldehyde	yes	no		(15)		
	54880								
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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99	19460	00000501216	lactic acid	yes	yes	no				
	62960									
100	24490	00000507014	sorbitol	yes	yes	no				
	88320									
101	36000	00000508073	ascorbic acid	yes	no	no				
102	17530	00000509007	glycerol	no	yes	no				
103	18100	00000508150	glycerol	yes	yes	no				
	55920									
104	58960	00000570944	decyltrimethylammonium bromide	no	no	no	6			
105	22780	00000571017	phthalic acid	yes	yes	no				
	70400									
106	24550	00000571014	stearic acid	yes	yes	no				
	89040									
107	25960	00000571036	urea	no	yes	no				
108	24880	00000571010	sebacic acid	no	yes	no				
109	23740	00000571526	propanediol	yes	yes	no				
	81840									
110	93520	00000590029 001019140	hydroxyethyl ether of polyethylene glycol	yes	no	no				
111	53600	00000600044	benzoin tetraacetic acid	no	no	no				
112	64015	00000601303	lactic acid	yes	no	no				
113	16780	00000641750	ellagic acid	yes	yes	no				
	52800									

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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114	55040	000006418-0	Formic acid	yes	no	no			
115	10090	000006419-0	acetic acid	yes	yes	no			
	30000								
116	13090	000006585-0	benzoic acid	yes	yes	no			
	37600								
117	21550	000006754-0	ethanol	no	yes	no			
118	23830	000006763-0	propanol	yes	yes	no			
	81882								
119	30295	000006764-0	acetone	yes	no	no			
120	49540	000006768-0	diethyl sulphoxide	no	no	no			
121	24270	000006977-0	salic 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	000007485-0	ethylene	no	yes	no			
126	10210	000007486-2	ethylene	no	yes	no			
127	26050	000007501-4	vinyl chloride	no	yes	no	ND		1 mg/ kg in final product
128	10060	000007507-0	aldehyde	yes	no		(1)		
129	17020	000007521-0	ethylene oxide	no	yes	no	ND		1 mg/ kg in (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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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								final product	
130	26110	0000075354	vinylidene chloride	no	yes	no	ND		(1)
131	48460	0000075437-6	1,1-difluoroethane	yes	no	no			
132	26140	0000075387	vinylidene fluoride	no	yes	no	5		
133	14380	0000075416	nylon chloride	no	yes	no	ND	1 mg/kg in final product	(10)
	23155								
134	43680	0000075456	1,1-dichloro-1,1-difluoroethane	yes	no	no	6	Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	0000075569	ethylene oxide	no	yes	no	ND	1 mg/kg in final product	
136	41680	0000076212	phor	yes	no	no			(3)
137	66580	0000077262-3	methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	yes	no	yes			(5)
138	93760	0000077407	butyl acetyl citrate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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139	14680	0000077	921-0	yes	yes	no					
	44160		acid								
140	44640	0000077	931-0	yes	no	no		(32)			
			acid, triethyl ester								
141	13380	0000077	199-6	yes	yes	no	6				
	25600										trimethylolpropane
	94960										
142	26305	0000078	081-0	no	no	no	0,05		Only to be used as a surface treatment agent	(1)	
143	62450	0000078	170-4	yes	no	no					
144	19243	0000078	279-5	no	yes	no	ND		1 mg/kg in final product		
	21640										methyl-1,3-butadiene
145	10630	0000079	061-1	no	yes	no	ND				
146	23890	0000079	001-1	yes	yes	no					
	82000										acid
147	10690	0000079	061-1	no	yes	no		(22)			
148	14650	0000079	180-0	no	no	no	ND			(1)	
149	19990	0000079	301-0	yes	yes	no	ND				
150	20020	0000079	441-1	yes	yes	no		(23)			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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151	13480	0000080205-7	bis(4-hydroxyphenyl)propane	no	yes	no	0,6		[^{F4} Not to be used for the manufacture of polycarbonate infant ^f feeding bottles ^g .]	
	13607									
152	15610	0000080407-9	dichlorodiphenyl sulphone	no	yes	no	0,05			
153	15267	0000080408-0	diaminodiphenyl sulphone	no	yes	no	5			
154	13617	0000080409-1	dihydroxydiphenyl sulphone	no	yes	no	0,05			
	16090									
155	23470	0000080656-8	pinene	no	yes	no				
156	21130	0000080661-6	acrylic acid, methyl ester	no	yes	no		(23)		
157	74880	0000084714-1	phthalic acid, dibutyl ester	yes	no	no	0,3	(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									(b)	contacting non-fatty foods; technical support agent in polyolefins in concentrations up to 0,05 % in the final product.
158	23380 76320	0000085	phthalic anhydride	yes	yes	no				
159	74560	0000085	phthalic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; plasticiser in single-use materials and

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

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h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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										agent in concentrations up to 0,1 % in the final product.
160	84800	0000087	salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
[^{F6} 161	92160	0000087	(4)-tartaric acid	yes	no	no]
162	65520	0000087	nitro	yes	no	no				
163	66400	0000088	2,2'-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088	2,6-aminobenzamide	yes	no	no	0,05		Only for use in PET for water and beverages	
165	23200 74480	0000088	phthalic acid	yes	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

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h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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166	24057	0000089	327-7 pyromellitic anhydride	yes	no	0,05				
167	25240	0000091	208-7 toluene diisocyanate	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	0000091	1274-9 diamino-6- phenyl-1,3,5- triazine	no	yes	no	5			(1)
169	16240	0000091	1397-4 dimethyl-4,4'- diisocyanatobiphenyl	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
170	16000	0000092	2488-6 dihydroxybiphenyl	no	yes	no	6			
171	38080	0000093	3582-3 benzoic acid, methyl ester	yes	no	no				
172	37840	0000093	3582-3 benzoic acid, ethyl ester	yes	no	no				
173	60240	0000094	4413-3 hydroxybenzoic 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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

			propyl ester							
174	14740	0000095	48-7 cresol	no	yes	no				
175	20050	0000096	0519 acrylic acid, allyl ester	no	yes	no	0,05			
176	11710	0000096	33 acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	0000096	41 ethylene carbonate	yes	no	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	0000096	49-5 thiobis(6-tert-	yes	no	yes	0,48			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			butyl-3-methylphenol)						
179	48800	0000097223-4	2,2'-dihydroxy-5,5'-dichlorodiphenylmethane	yes	no	yes	12		
[^{F7} 180	17160	0000097530-0	7-phenol	no	yes	no		(33)]
181	20890	0000097631-2	methacrylic acid, ethyl ester	yes	no	no		(23)	
182	19270	0000097654-0	hexanoic acid	no	yes	no			
183	21010	0000097841-9	methacrylic acid, isobutyl ester	yes	no	no		(23)	
184	20110	0000097881-6	methacrylic acid, butyl ester	yes	no	no		(23)	
185	20440	0000097901-6	methacrylic acid, diester with ethyleneglycol	yes	no	no	0,05		
186	14020	0000098451-4	tert-butylphenol	no	yes	no	0,05		
187	22210	000009883-9	methylstyrene	no	yes	no	0,05		
188	19180	0000099163-8	phthalic acid dichloride	yes	no	no		(27)	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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189	60200	0000099476-3	hydroxybenzoic acid, methyl ester	yes	no	no			
190	18880	0000099496-7	hydroxybenzoic acid	no	yes	no			
191	24940	0000100400-9	phthalic acid dichloride	no	yes	no	(28)		
192	23187	—	phthalic acid	no	yes	no	(28)		
193	24610	0000100542-5	styrene	no	yes	no			
194	13150	0000100551-6	benzyl alcohol	no	yes	no			
195	37360	0000100552-7	benzaldehyde	no	no	no			(3)
196	18670	0000100670-0	hexamethylene tetramine	no	yes	no	(15)		
	59280								
197	20260	0000101439-0	methacrylic acid, cyclohexyl ester	yes	no	no	0,05		
198	16630	0000101668-8	hexamethylene 4,4'-diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
199	24073	0000101900-6	epichlorohydrin diglycidyl ether	yes	no	no	ND	Not to be used	(8)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									for articles in contact with fatty foods for which [F1simulant D1 and/or D2] is laid down. For indirect food contact only, behind a PET layer.
200	51680	000010220849	408-9 diphenylthiourea	yes	no	yes	3		
201	16540	000010220910	409-0 diphenyl carbonate	no	yes	no	0,05		
202	23070	000010221326	432-6 phenylenedioxydiacetic acid	no	yes	no	0,05		(1)
203	13323	000010221419	433-9 bis(2-hydroxyethoxy)benzene	no	yes	no	0,05		
204	25180 92640	000010226033	460-3 'N',N'-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	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 [F3Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5OJ L 83, 22.3.2012, p. 1.]

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205	25385	00001024705	Hydramine	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	00001032110	acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05		
207	31920	00001032110	acrylic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)	(2)
208	18898	00001032110	(4-hydroxyphenyl) acetamide	no	yes	no	0,05		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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209	17050	0000104276-7	ethyl-1-hexanol	no	yes	no	30			
210	13390	0000105108-8	bis(hydroxymethyl)cyclohexane	no	yes	no				
	14880									
211	23920	0000105384-1	acetic acid, vinyl ester	no	yes	no		(1)		
212	14200	0000105602-1	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	0000106511-0	phthalic anhydride	no	yes	no				
216	14770	0000106744-5	o-cresol	no	yes	no				
217	15565	0000106446-7	1,2-dichlorobenzene	no	yes	no	12			
218	11590	0000106631-1	acetic acid, isobutyl ester	no	yes	no		(22)		
219	14570	0000106892-8	epichlorohydrin	yes	yes	no	ND		1 mg/kg in final product	(10)
	16750									
220	20590	0000106912-2	methacrylic acid	yes	yes	no	0,02			(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			2,3-epoxypropyl ester						
221	40570	0000106907-8	butane	yes	no	no			
222	13870	0000106498-9	butene	no	yes	no			
223	13630	0000106909-0	butadiene	no	yes	no	ND		1 mg/kg in final product
224	13900	0000107291-7	butene	no	yes	no			
225	12100	0000107101-1	acrylonitrile	yes	yes	no	ND		
226	15272	0000107115-2	ethylene diamine	yes	yes	no	12		
227	16990	0000107117-4	ethylene glycol	yes	yes	no		(2)	
228	13690	0000107183-0	butanediol	no	yes	no			
229	14140	0000107192-6	butyric acid	no	yes	no			
230	16150	0000108101-4	1,4-bis(2-aminoethyl)ethanol	yes	yes	no	18		
231	10120	0000108105-4	itaic acid, vinyl ester	no	yes	no	12		
232	10150	0000108124-7	itaic anhydride	yes	yes	no			
233	24850	0000108165-1	itaic anhydride	no	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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234	19960	000010833-6	maleic anhydride	no	yes	no		(3)		
235	14710	000010839-4	cresol	no	yes	no				
236	23050	000010845-2	phenylenediamine	no	yes	no	ND			
237	15910	000010846-3	2,4-dihydroxybenzene	no	yes	no	2,4			
	24072									
238	18070	000010855-4	glutaric anhydride	no	yes	no				
[^{F8} 239	19975	000010874-6	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
	25420									
	93720]									
240	45760	000010891-8	hexylamine	no	yes	no				
[^{F6} 241	22960	000010895-2	phenol	no	yes	no	3]
242	85360	000010948-4	butyric acid, dibutyl ester	yes	no	no		(32)		
243	19060	000010953-5	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	000010966-0	pentane	yes	no	no				
245	22900	000010967-1	pentene	no	yes	no	5			
246	25150	000010990-9	2-thiofuran	yes	yes	no	0,6			
247	24820	000011055-6	succinic acid	yes	yes	no				
	90960									
248	19540	000011061-7	maleic acid	yes	yes	no		(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.

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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	64800									
249	17290	0000110117-8	Fumaric acid	yes	yes	no				
	55120									
250	53520	0000110130-5	ethylenebisstearamide	yes	no	no				
251	53360	0000110131-6	ethylenebisoleamide	yes	no	no				
252	87200	0000110140-1	sebacic acid	yes	no	no				
253	15250	0000110160-1	diaminobutane	no	yes	no				
254	13720	0000110163-4	butanediol	yes	yes	no		(30)		
	40580									
255	25900	0000110183-3	hexane	no	yes	no	5			
256	18010	0000110191-8	glutaric acid	yes	yes	no				
	55680									
[^{F7} 257	13550	0000110198-5	propylene glycol	yes	yes	no				
	16660	0025265-71-8								
	51760]								
258	70480	0000111001-8	malonic acid, butyl ester	yes	no	no				
259	58720	0000111141-8	heptanoic acid	yes	no	no				
260	24280	0000111201-6	sebacic acid	no	yes	no				
261	15790	0000111401-0	dodecyltriminines	yes	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.

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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262	35284	00001114121	4121 aminoethyl)ethanolamine	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F1]simulant D1 and/or D2] is laid down. For indirect food contact only, behind a PET layer.	
263	13326	00001114616	4616 ethylene glycol	yes	no	no		(2)		
	15760									
	47680									
264	22660	0000111466-0	466-0 octene	no	yes	no	15			
265	22600	0000111487-5	487-5 octanol	no	yes	no				
266	25510	00001112476	476 ethylene glycol	yes	no	no				
	94320									

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 [F3Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4]Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5OJ L 83, 22.3.2012, p. 1.]

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267	15100	0000112430-1	decanol	no	yes	no			
268	16704	0000112441-4	dodecene	no	yes	no	0,05		
269	25090	0000112607	1,6-hexanediol	yes	yes	no			
	92350								
270	22763	0000112801	acetic acid	yes	yes	no			
	69040								
271	52720	0000112845	acetamide	yes	no	no			
272	37040	0000112856	acetic acid	yes	no	no			
273	52730	0000112867	acetic acid	yes	no	no			
274	22570	0000112969	decyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
275	23980	0000115007	polyethylene	no	yes	no			
276	19000	0000115151	isobutene	no	yes	no			
277	18280	0000115274	hexachlorocyclohexane	no	yes	no			ND
278	18250	0000115286	hexachlorocyclohexane	no	yes	no			ND
279	22840	0000115775	erythritol	yes	yes	no			
	71600								
280	73720	0000115908	phosphoric acid,	yes	no	no	ND		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1](#).]

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			trichloroethyl ester						
281	25120	0000116	hexafluoroethylene	yes	no	0,05			
282	18430	0000116	hexafluoropropylene	yes	no	ND			
283	74640	0000117	phthalic acid, bis(2-ethylhexyl) ester	yes	no	1,5	(32)	Only to be used as: (a)	(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	0000119	salicylic acid, methyl ester	yes	no	30		(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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285	66480	0000119247-1	yes	no	yes		(13)		
			methylene bis(4-methyl-6-tert-butylphenol)						
286	38240	0000119610-9	benzophenone	no	yes	0,6			
287	60160	0000120447-8	yes	no	no				
			hydroxybenzoic acid, ethyl ester						
288	24970	0000120614-1	terephthalic acid, dimethyl ester	yes	no				
289	15880	0000120180-9	no	yes	no	6			
	24051		dihydroxybenzene						
290	55360	0000121710-0	yes	no	no		(20)		
			lactic acid, propyl ester						
291	19150	0000121815-3	isophthalic acid	yes	no		(27)		
292	94560	0000122410-3	propylamine	yes	no	5			
293	23175	0000122410-3	phosphoric acid, triethyl ester	yes	no	ND		1 mg/kg in final product	(1)
294	93120	0000123428-4	no	yes	no		(14)		
			acetic acid, didodecyl ester						

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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295	15940	0000123134-9	1,4-dihydroxybenzene	yes	yes	no	0,6				
	18867										
	48620										
296	23860	0000123138-6	propionaldehyde	yes	yes	no					
297	23950	0000123160-6	phthalic anhydride	no	yes	no					
298	14110	0000123172-8	butyraldehyde	yes	yes	no					
299	63840	0000123176-1	ascorbic acid	yes	yes	no	no				
300	30045	0000123186-4	acetic acid, butyl ester	yes	yes	no	no				
301	89120	0000123195-5	acetic acid, butyl ester	yes	yes	no	no				
302	12820	0000123201-6	acetic acid	no	yes	no					
303	12130	0000124011-9	adipic acid	yes	yes	no					
	31730										
304	14320	0000124017-2	acrylic acid	yes	yes	no					
	41960										
305	15274	0000124024-4	1,4-methylenediamine	yes	yes	no	2,4				
	18460										
306	88960	0000124026-5	acetamide	yes	yes	no	no				
307	42160	0000124028-0	carbon dioxide	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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308	91200	000012653-6	acetate isobutyrate	yes	no	no			
309	91360	000012654-7	octaacetate	yes	no	no			
310	16390	000012623-7	dimethyl-1,3-propanediol	no	yes	no	0,05		
	22437								
311	16480	000012658-9	pentaerythritol	yes	yes	no			
	51200								
312	21490	000012698-7	acrylonitrile	yes	yes	no	ND		
313	16650	000012746-9	phenylsulphone	yes	yes	no	3		
	51570								
314	23500	000012791-3	pinene	no	yes	no			
315	46640	000012823-0	tert-butyl-p-cresol	yes	no	no	3		
316	23230	000013179-0	phthalic acid, diallyl ester	no	yes	no	ND		
317	48880	000013125-3	4-dihydroxybenzophenone	yes	no	yes	(8)		
318	48640	000013126-6	4-dihydroxybenzophenone	yes	no	no	(8)		
319	61360	000013127-7	4-hydroxybenzophenone	yes	no	yes	(8)		

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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F⁵OJ L 83, 22.3.2012, p. 1.]

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320	37680	000013660	7-azobicycloheptane	yes	no	no			
321	36080	000013766	6-acyloxyhexanoic acid, butyl ester	yes	no	no			
322	63040	000013822	7-acyloxyheptanoic acid, butyl ester	yes	no	no			
323	11470	000014088	8-acyloxyoctanoic acid, ethyl ester	no	yes	no		(22)	
324	83700	000014122	12-oleic acid	yes	no	yes	42		
325	10780	000014132	12-oleic acid, n-butyl ester	no	yes	no		(22)	
326	12763 35170	000014124	3-aminoethanol	yes	yes	no	0,05		Not to be used for articles in contact with fatty foods for which [F1]simulant D1 and/

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 [F3]Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4]Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5]OJ L 83, 22.3.2012, p. 1.]

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									or D2] is laid down. For indirect food contact only, behind a PET layer.
327	30140	000014178-6	lactic acid, ethyl ester	yes	no	no			
328	65040	000014182-0	lactic acid	yes	no	no			
329	59360	000014216-2	lactic acid	yes	no	no			
330	19470	000014310-7	lactic acid	yes	yes	no			
	63280								
331	22480	000014318-8	nonanol	no	yes	no			
332	69760	000014328-2	ethyl alcohol	yes	no	no			
333	22775	000014462-7	lactic acid	yes	yes	no	6		
	69920								
334	17005	000015166-4	ethyleneimine	yes	no	no	6	ND	
335	68960	000030102-0	oleamide	yes	no	no			
336	15095	000033418-5	decanoic acid	yes	yes	no			
	45940								

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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337	15820	000034549-6	49-6	no	yes	no	0,05			
			difluorobenzophenone							
338	71020	000037340-9	40-9	yes	no	no				
			paratolonic acid							
339	86160	000040951-2	51-2	yes	no	no				
			silicon carbide							
[^{F9} 340	47440	000046158-5	58-5	no	yes	no	60]
			isocyanide							
341	13180	000049866-8	66-8	no	yes	no	0,05			
	22550		heptene							
342	14260	000050244-3	44-3	yes	no	no		(29)		
			lactone							
343	23770	000050416-2	16-2	no	yes	no	0,05			
			propanediol							
[^{F6} 344	13810	000050516-7	16-7	no	yes	no	0,05	15		(21)
	21821]		butanediol formal					30		
345	35840	000050630-9	30-9	yes	no	no				
			acetic acid							
346	10030	000051410-8	10-8	no	yes	no				
			acetic acid							
347	13050	000052844-9	44-9	no	yes	no		(21)		
	25540		lactic acid							
348	22350	000054463-8	63-8	yes	yes	no				
	67891		acetic acid							
349	25550	000055210-7	10-7	no	yes	no		(21)		
			lactic anhydride							
350	63920	000055719-5	19-5	yes	no	no				
			lactic acid							
351	21730	000056345-1	45-1	no	yes	no	ND		Only to be used	(1)
			methyl-1-butene							

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									in polypropylene	
352	16360	0000576226-1	no dimethylphenol	yes	no	0,05				
353	42480	0000584008-1	nicotinic acid, rubidium salt	no	no	12				
354	25210	0000584284-9	no toluene diisocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)	
355	20170	0000585071-1	no acrylic acid, tert-butyl ester	yes	no		(23)			
356	18820	0000592141-6	no hexene	yes	no	3				
357	13932	0000598332-3	no buten-2-ol	yes	no	ND		Only to be used as a co-monomer for the preparation of polymeric additive	(1)	
358	14841	0000599464-4	no cumylphenol	yes	no	0,05				

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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359	15970 48720	000061149-4	yes	yes	no		(8)		
			dihydroxybenzophenone						
360	57920	000062047-7	yes	no	no				
			glycerol triheptanoate						
361	18700	000062911-8	no	yes	no	0,05			
			hexanediol						
362	14350	000063048-0	no	yes	no				
			carbon monoxide						
363	16450	000064610-0	no	yes	no	5			
			dioxolane						
[^{F6} 364	15404	000065217-3,6-	no	yes	no	5		Only to be used as:] a co-monomer in poly(ethylene-co-isorbide terephthalate); a co-monomer at levels of up to 40 mole % of the diol
			dianhydrosorbitol					(a)	
								(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									component in combination with ethylene glycol and/or 1,4-bis(hydroxymethyl)cyclohexane for the production of polyesters.
									Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol.
365	11680	0000689	Octylic acid, isopropyl ester	no	yes	no		(22)	
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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366	22150	0000691	1437-2 methyl-1-pentene	no	yes	no	0,05			
367	16697	0000693	1223-2 dodecanedioic acid	no	yes	no				
368	93280	0000693	1316-1 Propionic acid, dioctadecyl ester	no	no	yes		(14)		
369	12761	0000693	1427-2 aminododecanoic acid	no	yes	no	0,05			
370	21460	0000760	09310 acrylic anhydride	no	yes	no		(23)		
371	11510	0000818	18610 acrylic acid, monoester with ethyleneglycol	no	yes	no		(22)		
	11830									
372	18640	0000822	2106-0 hexamethylene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	0000840	265-3 naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	0000868	17116 acrylic acid,	no	yes	no		(23)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			monoester with ethyleneglycol						
375	15130	0000872405-9	decene	no	yes	no	0,05		
[^{F8} 376	66905	0000872450-4	methylpyrrolidone	yes	no	no	60]
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 reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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378	21970	0000923	302-4 methylmethacrylamide	no	yes	no	0,05			
379	21940	0000924	442-5 methylolacrylamide	no	yes	no	ND			
380	11980	0000925	60-11 acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931	814-0 1,8-dioctane	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			
384	40000	0000991	284-4 bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			
385	11530	0000999	61-1 acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML (1) expressed as the sum of acrylic	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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									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	0001034	gallic acid, octyl ester	yes	no	no		(20)		
387	26155	0001072	463-5 vinylimidazole	no	yes	no	0,05			(1)
388	25080	0001120	436-1 tetradecene	no	yes	no	0,05			
389	22360	0001141	238-4 naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	0001166	5215 acid,	yes	no	no		(20)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			dodecyl ester							
[^{F1} 391]	22932	0001187	2,2,4,4-tetrafluoro-1-methylperfluorovinyl ether	yes	no	0,05			Only to be used in: — —] anti-stick coatings; fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio is 1 dm ² surface in contact with at least 150 kg food.
392	72800	0001241	Phosphoric acid, diphenyl 2-	no	yes	2,4				

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			ethylhexyl ester						
393	37280	000130257810	nitro	yes	no	no			
394	41280	000130561210	hydroxide	yes	no	no			
395	41520	000130578310	oxide	yes	no	no			
396	64640	000130942810	hydroxide	yes	no	no			
397	64720	000130942810	oxide	yes	no	no			
398	35760	000130964110	trioxide	yes	no	no	0,04		SML (6) expressed as antimony
399	81600	000131058310	hydroxide	yes	no	no			
400	86720	000131057110	hydroxide	yes	no	no			
401	24475	000131382110	sulphide	no	yes	no			
402	96240	000131421210	oxide	yes	no	no			
403	96320	000131421310	sulphide	yes	no	no			
404	67200	000131733110	disulphide	yes	no	no			
405	16690	000132174110	benzene	yes	no	no	ND		SML (1) expressed as the sum of divinylbenzene

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.
406	83300	0001323432-3	propyleneglycol monostearate	yes	no	no				
407	87040	0001330561-4	sodium tetraborate	yes	no	no	(16)			
408	82960	0001330482-9	propyleneglycol monooleate	yes	no	no				
409	62240	0001332137-2	oxide	yes	no	no				
[^{F6} 410]	62720	0001332158-1	alcohol	yes	no	no				Particles] can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl alcohol

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food.
411	42080	0001333	carbon black	yes	no	no			Primary particles of 10 – 300 nm which are aggregated to a size 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.](#)

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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										100 – 1 200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell,
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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									determined according to a generally recognised method 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	5235 copper iodide	yes	no	no	(6)		
413	35600	0001336	2116 antimony hydroxide	yes	no	no			
414	87600	0001338	5012 sodium monolaurate	yes	no	no			
415	87840	0001338	4114 sodium monostearate	yes	no	no			
416	87680	0001338	4114 sodium monooleate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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417	85680	0001343	18-2 sulfuric acid	yes	no	no			
418	34720	0001344	28-1 zinc oxide	yes	no	no			
419	92150	0001401	55-4 fatty acids	yes	no	no			According to the JECFA specifications
420	19210	0001459	03-4 phthalic acid, dimethyl ester	yes	no	no	0,05		
[^{F9} 421	13000	0001477	53-0 benzenedimethanamine	no	yes	no		(34)	I
422	38515	0001533	45-5 bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05		(2)
423	22937	0001623	05-8 isopropylperfluorovinyl ether	no	yes	no	0,05		
424	15070	0001647	16-1 decadiene	no	yes	no	0,05		
425	10840	0001663	09-4 acrylic acid, tert-butyl ester	no	yes	no		(22)	
426	13510	0001675	2-3 bis(4-hydroxyphenyl)propane	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005 ^a
	13610		bis(2,3-epoxypropyl) ether						

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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427	18896	00016794	51-2 (hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	00017091	70-52 tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no				
429	13210	00017615	73-4 aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	00018431	08-34 tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	yes	no	yes	5			
431	61600	00018432	05-6 hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)		
432	12280	00020354	75-8 anhydride	no	yes	no				
433	68320	00020826	70-1 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6			
434	20410	00020828	17-1 acrylic acid, diester with 1,4-butanediol	yes	no	no	0,05			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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435	14230	00021232	2,4-dichlorobenzaldehyde sodium salt	no	yes	no		(4)		
436	19480	00021461	maleic acid, vinyl ester	no	yes	no				
437	11245	00021560	maleic acid, dodecyl ester	no	yes	no	0,05			(2)
[^{F8} 438	13303	00021625	bis(2,6-diisopropylphenyl)carbodiimide	no	yes	no	0,05		Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product 2,6-diisopropylaniline	
439	21280	00021777	methacrylic acid, phenyl ester	no	yes	no		(23)		
440	21340	00022102	methacrylic acid, propyl ester	no	yes	no		(23)		
441	38160	00023156	benzoic acid, propyl ester	yes	no	no				
442	13780	00024251	1,4-butanediol	no	yes	no	ND		Residual content = 1	(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			bis(2,3-epoxypropyl)ether					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	0002440222-4	hydroxy-5'-methylphenyl)benzotriazole	yes	no	no	(12)		
445	83440	0002466993-3	phosphoric acid	no	yes	no			
446	10750	0002495354-4	acrylic acid, benzyl ester	no	yes	no	(22)		
447	20080	0002495354-4	acrylic acid, benzyl ester	no	yes	no	(23)		
448	11890	0002499559-4	acrylic acid, n-octyl ester	no	yes	no	(22)		
[^{F7} 449	49840	0002500488-4	octadecyl disulphide	no	yes	no	0,05]
450	24430	0002561888-8	Basic anhydride	no	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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451	66755	0002682	220-4	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions	
[^{F8} 452	38885	0002725	224-6	yes	no	no	5]
453	26320	0002768	0271	no	yes	no	0,05			(10)
454	12670	0002855	113-2	no	yes	no	6			
455	20530	0002867	4512	yes	no	no	ND			
456	10810	0002998	0875	no	yes	no		(22)		
457	20140	0002998	1817	yes	no	no		(23)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			butyl ester						
458	36960	0003061	benzamide	no	no				
459	46870	000313531	tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no				
460	14950	0003173	hexyl isocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
461	22420	000317347	naphthalene diisocyanate	no	yes		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
462	26170	0003195	vinyl-N-methylacetamide	no	yes	no	0,02		(1)
463	25840	0003290	trimethylolpropane trimethacrylate	no	yes	no	0,05		
464	61280	0003293	hydroxy-4-	yes	no	yes		(8)	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			n-hexyloxybenzophenone						
465	68040	00033337621	1-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no			
466	50640	0003648188	1-octyltin dilaurate	yes	no	no		(10)	
467	14800	0003724650	4-hydroxybenzoic acid	yes	yes	no	0,05		(1)
	45600								
468	71960	000382526	26-fluorocyclohexanoic acid, ammonium salt	no	no	no			Only to be used in repeated use articles, sintered at high temperatures
469	60480	000386429021	2-hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)	
470	60400	000389621025	2-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)	
471	24888	0003965555-7	5-sulphoisophthalic	no	yes	no	0,05		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			acid, monosodium salt, dimethyl ester							
472	66560	0004066202-8	methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074401-2	acid, divinyl ester	no	yes	no	ND		5 mg/ kg in final product. Only to be used as co- monomer.	(1)
474	43600	000408043(3-3	chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			
475	19110	0004098171-9	isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
476	16570	0004128471-8	diisocyanate	no	yes	no		(17)	1 mg/ kg in final product expressed as	(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									isocyanate moiety	
477	46720	0004130246	2,4-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8			(1)
478	60180	0004191473-5	hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	0004196261-6	anhydride	no	yes	no				
480	46790	0004221380	2,4-di-tert-butylphenyl ester	yes	no	no				
481	13060	0004422195-5	benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5-benzenetricarboxylic acid	(1)
482	21100	0004655349	methacrylic acid, isopropyl ester	yes	no	no		(23)		
483	68860	0004724448-5	octylphosphonic acid	yes	no	no	0,05			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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484	13395	0004767203-7	bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)
485	13560	000512430-1	4,4'-dihydroxydiphenylmethane diisocyanate	no	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
	15700									
486	54005	000513644-1	N-palmitamide-N'-stearamide	yes	no	no				
487	45640	000523229-5	cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05			
488	53440	000551818-3	ethylenebispalmitamide	yes	no	no				
489	41040	000574346-2	butyrate	yes	no	no				
490	16600	000587345-1	4,4'-dihydroxydiphenylmethane diisocyanate	no	no	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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491	82720	00061824	11-2	yes	no	no				
			propyleneglycol distearate							
492	45650	00061972	30-4	yes	no	no	0,05			
			cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester							
493	39200	00062004	40-2	yes	no	no	1,8			
			hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride							
494	62140	00063033	21-6	no	no	no				
			hypophosphorous acid							
495	35160	00066426	31-5	yes	no	no	5			
			amino-1,3-dimethyluracil							
496	71680	00066831	10-8	no	no	no				
			polyacrylate tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]							
497	95020	00068462	50-4	yes	no	no	5			Only to be used in single-use gloves
			trimethyl-1,3-pentane diol diisobutyrate							

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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498	16210	0006864337-5	no dimethyl-4,4'- diaminodicyclohexylmethane	yes	no	0,05		Only to be used in polyamides	(5)
499	19965 65020	0006915117	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	0007128261-5	bis(5-tert-butyl-2-benzoxazolyl)thiophene	yes	no	yes	0,6		
501	34480	—	aluminium fibers, flakes and powders	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

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h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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502	22778	0007456468-0	oxybis(benzenesulphonyl azide)	no	yes	no	0,05			(1)
503	46080	0007585339-9	dextrin	yes	no	no				
504	86240	0007631860-0	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	0007631800-0	calcium bisulphite	yes	no	no		(19)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.]

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h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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506	86920	0007632s00i0m	nitrite	yes	no	no	0,6			
507	59990	0007647h01i0	hydrochloric acid	yes	no	no				
508	86560	0007647s0i0m	bromide	yes	no	no				
509	23170	0007664p0s0	phosphoric acid	yes	yes	no				
	72640									
510	12789	0007664a0i0m	ammonia	yes	yes	no				
	35320									
511	91920	0007664s0p0	perboric acid	yes	no	no				
512	81680	0007681p0i0m	potassium iodide	yes	no	no		(6)		
513	86800	0007681s0i0m	sodium iodide	yes	no	no		(6)		
514	91840	0007704s0p0	sulphur	yes	no	no				
515	26360	0007732w0t0	water	yes	yes	no			In compliance with Directive 98/83/EC ^b	
	95855									
516	86960	0007757s0i0m	sulphite	yes	no	no		(19)		
517	81520	0007758p0i0m	potassium bromide	yes	no	no				
518	35845	0007771a0i0m	ascorbic acid	yes	no	no				
519	87120	0007772s0i0m	thiosulphate	yes	no	no		(19)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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520	65120	0007773	3004	mercuric chloride	yes	no	no				
521	58320	0007782	4241	zinc white	yes	no	no				
522	14530	0007782	5105	fine	no	yes	no				
523	45195	0007787	7004	copper bromide	yes	no	no				
524	24520	0008001	3217	lanolin oil	no	yes	no				
525	62640	0008001	3006	Japan wax	yes	no	no				
526	43440	0008001	1756	linseed oil	yes	no	no				
527	14411	0008001	1794	petroleum oil	yes	yes	no				
	42880										
528	63760	0008002	1435	linseed oil	yes	no	no				
529	67850	0008002	1507	lanolin wax	yes	no	no				
530	41760	0008006	4481	beeswax	yes	no	no				
531	36880	0008012	1893	beeswax	yes	no	no				
532	88640	0008013	0718	lanolin oil, epoxidised	yes	no	no	60 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant

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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

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h [F⁵OJ L 83, 22.3.2012, p. 1.]

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										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, the SML is lowered to 30 mg/kg.
										Oxirane < 8 %,
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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									iodine number < 6.
533	42720	0008015869	Sebacic wax	yes	no	no			
534	80720	0008017061	phosphoric acids	yes	no	no			
535	24100	0008050097		yes	yes	no			
	24130								
	24190								
	83840								
536	84320	0008050456	hydrogenated, ester with methanol	yes	no	no			
537	84080	0008050268	ester with pentaerythritol	yes	no	no			
538	84000	0008050316	ester with glycerol	yes	no	no			
539	24160	0008052106	tall oil	no	yes	no			
540	63940	0008062155	phosphoric acid	yes	no	no	0,24		Only to be used as dispersant for plastics dispersions

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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541	58480	000900000115	gum arabic	yes	no	no				
542	42640	000900000117	cellulose methylcellulose	yes	no	no				
543	45920	000900000118	cellulose	yes	no	no				
544	58400	000900000119	gum	yes	no	no				
545	93680	000900000120	gum	yes	no	no				
546	71440	000900000121	gum	yes	no	no				
547	55440	000900000122	gum	yes	no	no				
548	42800	000900000123	gum	yes	no	no				
549	80000	000900000124	polyethylene wax	yes	no	no				
550	81060	000900000125	polypropylene wax	yes	no	no				
551	79920	000900000126	poly(ethylene glycol)	yes	no	no				
552	81500	000900000127	polyvinylpyrrolidone	yes	no	no				The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC ^c
553	14500	000900000128	cellulose	yes	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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	43280								
554	43300	00090043118	acetate butyrate	yes	no	no			
555	53280	0009004677	cellulose	yes	no	no			
556	54260	0009004684	hydroxyethylcellulose	yes	no	no			
557	66640	00090045015	ethylcellulose	yes	no	no			
558	60560	0009004620	hydroxyethylcellulose	yes	no	no			
559	61680	0009004642	propylcellulose	yes	no	no			
560	66700	0009004653	hydroxypropylcellulose	yes	no	no			
561	66240	0009004675	cellulose	yes	no	no			
562	22450	0009004700	cellulose	yes	yes	no			
563	78320	0009004907	ethylsuccinylsuccinate monoricinoleate	yes	no	yes	42		
564	24540	0009005268	edible	yes	yes	no			
	88800								
565	61120	0009005370	hydroxyethyl starch	yes	no	no			
566	33350	0009005421	lactic acid	yes	no	no			
567	82080	0009005137	propyleneglycol alginate	yes	no	no			
568	79040	0009005645	polyethylsorbitan monolaurate	yes	no	no			
569	79120	0009005656	polyethylsorbitan monooleate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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570	79200	00090056067	poly(7-ethylsorbitan monopalmitate)	yes	no				
571	79280	00090056078	poly(8-ethylsorbitan monostearate)	yes	no				
572	79360	00090056073	poly(3-ethylsorbitan trioleate)	yes	no				
573	79440	00090056074	poly(4-ethylsorbitan tristearate)	yes	no				
574	24250 84560	00090060166	poly(6,6-natural)	yes	yes	no			
575	76721	00631486029	polydimethylsiloxane (Mw > 6 800 Da)	yes	no				Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)
576	60880	00090324212	hydroxyethylmethylcellulose	yes	no				
577	62280	00090441570	isobutylene-butene copolymer	yes	no	no			
578	79600	00090460190	poly(9-ethyltridecyl ether phosphate)	yes	no	5			For materials and articles intended for

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl 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	00100166203	dextrin	yes	no	no			
581	36800	00100226118	barium nitrate	yes	no	no			
582	50240	00100394335	octyltin bis(2-ethylhexyl maleate)	yes	no	no	(10)		
583	40400	00100436665	boron nitride	yes	no	no	(16)		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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584	13620	00100435	3503	yes	yes	no		(16)		
	40320		acid							
585	41120	00100435	5104	yes	no	no				
			chloride							
586	65280	00100435	8402	yes	no	no				
			hypophosphite							
587	68400	00100944	4508	yes	no	yes	5			
			lysine							
588	64320	00103771	1102	yes	no	no		(6)		
			iodide							
589	52645	00104360	0815	yes	no	no				
			eicosenamide							
590	21370	00105955	0010	yes	no	no	ND			(1)
			acrylic acid, 2-sulphoethyl ester							
591	36160	00106055	0001	yes	no	no				
			stearate							
592	34690	00110975	0009	yes	no	no				
			magnesium carbonate hydroxide							
593	44960	00111040	0001	yes	no	no				
			oxide							
594	65360	00111290	0005	yes	no	no				
			oxide							
595	19510	00111321	0003	yes	no	no				
			cellulose							
596	95935	00111380	0001	yes	no	no				
			gum							
597	67120	00120012	0002	yes	no	no				
			lactate							

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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598	41600	0012004 0037293	441-17 321-14	lead-iron sulfate-aluminate	yes	no	no			
599	36840	0012007	551-1	boron tetraborate	yes	no	no		(16)	
600	60030	0012072	901-1	barium magnesite	yes	no	no			
601	35440	0012124	071-0	antimony bromide	yes	no	no			
602	70240	0012198	231-5	zinc oxide	yes	no	no			
603	83460	0012269	781-2	pyrene dihydro	yes	no	no			
604	60080	0012304	611-3	hydrolytic catalysts	yes	no	no			
605	11005	0012542	201-1	dicarboxylic acid, dicyclopentenyl ester	no	yes	no	0,05		(1)
606	65200	0012626	881-9	barium hydroxide	yes	no	no			
607	62245	0012751	211-3	lithium phosphide	yes	no	no			Only to be used in PET polymers and copolymers
608	40800	0013003	411-8	butylidene- bis(6- tert- butyl-3- methylphenyl- ditridecyl phosphite)	yes	no	yes	6		
609	83455	0013445	561-2	phosphorus 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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610	93440	0013463	1677	tin dioxide	yes	no	no			
611	35120	0013560	349-1	aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no			
612	16694	0013811	502	divinyl-2-imidazolidinone	no	yes	no	0,05		(10)
613	95905	0013983	1710	histidine	yes	no	no			
614	45560	0014464	461	isobaltes	yes	no	no			
615	92080	0014807	16-6	talc	yes	no	no			
616	83470	0014808	607z	quartz	yes	no	no			
617	10660	0015214	289-8	acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05		
618	51040	0015535	179-2	octyltin mercaptoacetate	yes	no	no		(10)	
619	50320	0015571	158-1	octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)	
620	50720	0015571	160-5	octyltin dimaleate	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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

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h [F⁵OJ L 83, 22.3.2012, p. 1.]

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621	17110	0016219575-3	ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	0016260009-6	palmitamide	no	yes	no	5			
623	52640	0016389488-1	zinc stearate	yes	no	no				
624	18897	0016712664-4	hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	0017194400-2	zinc hydroxide	yes	no	no				
626	57800	0018641574-1	glycerol tribehenate	yes	no	no				
627	59760	0019569411-2	zinc stearate	yes	no	no				
628	96190	0020427388-1	zinc hydroxide	yes	no	no				
629	34560	0021645411-2	zinc hydroxide	yes	no	no				
630	82240	0022788412-8	propyleneglycol dilaurate	yes	no	no				
631	59120	0023128176-7	hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45			
632	52880	0023676409-7	ethoxybenzoic acid, ethyl ester	yes	no	no	3,6			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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633	53200	0023949	266-8	yes	no	yes	30			
			ethoxy-2'-ethyloxanilide							
634	25910	0024800	44-0	polyethylene glycols		no				
635	40720	0025013	46-5	butyl-4-hydroxyanisole	yes	no	no	30		
636	31500	0025134	51-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester
637	71635	0025151	26-6	polybutyl sebacate	no	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down
638	23590	0025322	68-3	polyethylene glycols		no				
	76960									

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 [F3 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4 Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5 OJ L 83, 22.3.2012, p. 1.]

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639	23651 80800	0025322	polypropylene	no	no			
640	54930	0025359	formaldehyde-1-naphthol, copolymer	no	no	0,05		
[^{F1} 641]	22331	0025513	copolymer 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]
642	64990	0025736	maleic anhydride-styrene, copolymer, sodium salt	yes	no	no		The fraction with molecular weight below 1 000 Da [^{F1} shall] not exceed 0,05 % (w/w)
643	87760	0026266	65700 tan monopalmitate	yes	no	no		
644	88080	0026266	65700 tan trioleate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

Status: Point in time view as at 14/09/2016.

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645	67760	0026401865	n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no		(11)		
646	50480	0026401478	octyltin bis(isooctyl mercaptoacetate)	yes	no	no		(10)		
647	56720	0026402363	glycerol monohexanoate	yes	no	no				
648	56880	0026402366	glycerol mono-octanoate	yes	no	no				
649	47210	0026427407	ethylhexanoic acid polymer	yes	no	no			Molecular unit = $(C_8H_{18}S_3Sn_2)_n$ (n = 1,5-2)	
650	49600	002663601	dimethylbis(isooctyl mercaptoacetate)	yes	no	no		(9)		
651	88240	002665801	sofitan tristearate	yes	no	no				
652	38820	002674153	(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	yes	no	yes	0,6			
653	25270	0026747290	toluene diisocyanate dimer	no	yes	no		(17)	1 mg/kg in final product expressed as	(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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										isocyanate moiety
654	88600	0026836	471-01	yes	no	no				
			monostearate							
655	25450	0026896	481-01	no	no	no	0,05			
			1,4-bis(4-chlorophenyl)ethane							
656	24760	0026914	431-01	yes	no	no	0,05			
			4-sulphonic acid							
657	67680	0027107	807-01	yes	no	no		(11)		
			n-octyltin tris(2-ethylhexyl mercaptoacetate)							
658	52000	0027176	871-01	no	no	no	30			
			4-cyanobenzene sulphonic acid							
659	82800	0027194	471-07	yes	no	no				
			propyleneglycol monolaurate							
660	47540	0027458	491-01	yes	no	yes	0,05			
			dodecyl disulphide							
661	95360	0027676	621-06	yes	no	yes	5			
			tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione							
662	25927	0027955	191-18	no	yes	no	0,005		Only to be used in polycarbonates	(1)
			tris(4-hydroxyphenyl)ethane							

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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663	64150	00282901701	1,7-dihydroxycyclohexanecarboxylic acid	yes	no	no			
664	95000	002893167	1,6-hexamethylene trimethacrylate-methyl methacrylate copolymer	no	no	no			
665	83120	0029013128-3	propyleneglycol monopalmitate	yes	no	no			
666	87280	0029116508	sebacic diol diolate	yes	no	no			
667	55190	002920402	1,3-bis(sn)-sn-glycerol-3-yl sebacate	yes	no	no			
668	80240	0029894357	polyglycerol ricinoleate	yes	no	no			
669	56610	0030233648	glycerol monobehenate	yes	no	no			
670	56800	0030899628	glycerol monolaurate diacetate	yes	no	no	(32)		
671	74240	0031570064	phosphoric acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no			
672	76845	0031831515	polyester of 1,4-butanediol with caprolactone	yes	no	no	(29) (30)	The fraction with molecular weight below 1 000 Da [F1 shall]	

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 [F3]Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4]Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5]OJ L 83, 22.3.2012, p. 1.]

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									not exceed 0,5 % (w/w)
673	53670	0032509	16-1 polyethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6		
674	46480	0032647	17-1 azylidene sorbitol	yes	no	no			
675	38800	0032687	18-1 bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15		
676	50400	0033568	19-1 octyltin bis(isooctyl maleate)	yes	no	no		(10)	
677	82560	0033587	20-1 propyleneglycol dipalmitate	yes	no	no			
678	59200	0035074	21-2 hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	yes	no	yes	6		
679	39060	0035958	30-6 bis(2-hydroxy-3,5-	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.]

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			di-tert-butylphenyl)ethane						
680	94400	0036443682-4	1,3-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]ethylene glycol	yes	no	no	9		
681	18310	0036653482-4	hexadecanol	no	yes	no			
682	53270	0037205604-2	hydroxyethylcellulose	yes	yes	no			
683	66200	003720604-2	hydroxymethylcellulose	yes	yes	no			
684	68125	0037244406-5	melingsyenite	yes	no	no			
685	85950	0037296517-2	fluoride 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 with food.
686	61390	0037353540-6	hydroxymethylcellulose	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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687	13530 13614	0038103206	206-9 bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05			
688	92560	0038613077	3077-13 bis(3,4-di-tert-butylphenyl)-4,4'-biphenylene diphosphonite	yes	no	yes	18			
689	95280	0040601175	1175-51 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	0041484435	4435-04 bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	no	yes	yes	2,4			
691	13600	0047465397	5397-4 bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8			
692	52320	0052047250	47250-13 dodecylphenylindole	yes	no	yes	0,06			
693	88160	0054140506	506-14 osafitan tripalmitate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.]

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1](#).]

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694	21400	0054276	3516 acrylic acid, sulphopropyl ester	yes	no	0,05			(1)
695	67520	0054849	3806 trimethyltin tris(isooctyl mercaptoacetate)	no	no		(9)		
696	92205	0057569	4014 phthalic acid, diester with 2,2'- methylenebis(4- methyl-6- tert- butylphenol)	no	no				
697	67515	0057583	3403 trimethyltin tris(ethylhexyl mercaptoacetate)	no	no		(9)		
698	49595	0057583	3504 dimethyltin bis(ethylhexyl mercaptoacetate)	no	no		(9)		
699	90720	0058446	6209 stearyl benzoyl methane		no				
700	31520	0061167	5816 folic acid, 2-tert- butyl-6- (3-tert- butyl-2- hydroxy-5- methylbenzyl)-4- methylphenyl ester	yes	no	yes	6		
701	40160	0061269	0612 bis(2,2,6,6- tetramethyl-4-	yes	no	no	2,4		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer						
702	87920	00617526	6814 sorbitan yes tetrastearate	no	no				
703	17170	00617884	874 fatty acids, coco	no	yes	no			
704	77600	00617885	875 polyethylene glycol ester of hydrogenated castor oil	no	no	no			
705	10599/90 10599/91	00617884	884 fatty, unsaturated (C ₁₈), dimers, non hydrogenated, distilled and non- distilled	no	yes	no	(18)		(1)
706	17230	00617904	613 fatty acids, tall oil	no	yes	no			
707	46375	00617905	52 diatomaceous earth	no	no	no			
708	77520	00617911	616 polyethylene glycol ester of castor oil	no	no	no	42		

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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709	87520	0062568	solbutan monobenate	yes	no	no			
710	38700	0063397	carbutoxyethyl bis(isooctyl mercaptoacetate)	yes	no	yes	18		
711	42000	0063438	carbutoxyethyl tris(isooctyl mercaptoacetate)	yes	no	yes	30		
712	42960	0064147	oil, dehydrated	yes	no	no			
[^{F6} 713	43480	0064365 0007440	hard coal 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 Regulation (EU) No 231/2012 ^d with

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									exception of ash content which can be up to 10 % (w/w).
714	84400	0064365	FD 1719, hydrogenated, ester with pentaerythritol	yes	no	no			
715	46880	0065140	391-01-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6		
716	60800	0065447	17(20)-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30		
717	84210	0065997	FD 311, hydrogenated	yes	no	no			
718	84240	0065997	FD 319, hydrogenated, ester	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			with glycerol						
719	65920	0066822	260-4 yes no no methacryloyloxyethyl- N,N-dimethyl- N-carboxymethylammonium chloride, sodium salt - octadecyl methacrylate- ethyl methacrylate- cyclohexyl methacrylate- N-vinyl-2- pyrrolidone, copolymers	yes	no	no			
720	67360	0067649	604- n- dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no	(25)		
721	46800	0067845	395-6- tert- butyl-4- hydroxybenzoic acid, hexadecyl ester	yes	no	no			
722	17200	0068308	651-2 acids, soya	no	yes	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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723	88880	0068412	starch, yes hydrolysed	no	no				
724	24903	0068425	syrups, no hydrolysed starch, hydrogenated	yes	no			In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ^e	

[^{F10}]

726	83599	0068442	products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes	(9)		
727	43360	0068442	hydrolysed regenerated	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										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.
729	75105	0068515 0026761	Phthalic acid diesters with primary, saturated C ₉ -C ₁₁ 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			90 % C ₁₀					(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
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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									(c)	by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
730	66930	0068554	47011 methylsilsesquioxane	no	yes	no				Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane
731	18220	0068564	488-5 heptylaminoundecanoic acid	no	yes	no	0,05			(2)
732	45450	0068610	051-5 cresol-dicyclopentadiene-isobutylene, copolymer	yes	no	yes	5			
733	10599/92	0068783	4115 fatty, unsaturated (C ₁₈), dimers,	no	yes	no		(18)		(1)
	10599/93									

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			hydrogenated, distilled and non- distilled						
734	46380	0068855	544-0 calcium earth, soda ash flux- calcined	no	no				
735	40120	0068951	551-8 bis(2-ethylhexyl)ethylene glycol hydroxymethylphosphonate	no	no				
736	50960	0069226	44-4 octyltin ethylene glycol bis(mercaptoacetate)	yes	no	no		(10)	
737	77370	0070142	204-6 polyethylene glycol-30 dipolyhydroxystearate	yes	no	no			
738	60320	0070321	282-7 hydroxy-3,5- bis(1,1- dimethylbenzyl)phenyl]benzotriazole	yes	no	yes	1,5		
739	70000	0070331	292-1 oxamidobis[ethyl-3- (3,5- di-tert- butyl-4- hydroxyphenyl)- propionate]	yes	no	no			
740	81200	0071878	309-8 [(1,1,3,3- tetramethylbutyl)amino]-1,3,5- triazine-2,4- diyl]- [(2,2,6,6- tetramethyl-4-	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.

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			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	007830124,44-	tetramethyl-20- (2,3- epoxypropyl)-7- oxa-3,20- diazadispiro- [5.1.11.2]- heneicosan-21- one, polymer	yes	no	yes	5		
743	38950	0079072594-	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

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1](#).]

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									Table 4 of Annex I	
745	68145	0080410237-2	2,2',3,3'-nitri(triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite)	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	
746	38810	0080693606-2	1,2,6-di-tert-butyl-4-methylphenyl)pentacerythritol diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	
747	47600	008403046-5	1,5-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)		
748	12765	00844341-28	4-(2-aminoethyl)- β -alanine, sodium salt	no	yes	no	0,05			
749	66360	0085209221-2	2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1](#)).]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1](#).]

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750	66350	0085209293-4	yes	no	no	5			
			methylenebis(4,6-di-tert-butylphenyl) lithium phosphate						
751	81515	0087189251	yes	no	no				
			zinc glycerolate						
[^{F1} 752	39890	008782644-1 0069158-41-4 0054686-97-4 0081541-12-0	yes	yes	no]
			bis(methylbenzylidene)sorbitol						
753	62800	00927044011	yes	no	no				
			calcined kaolin						
754	56020	0099880546	yes	no	no				
			glycerol dibehenate						
755	21765	010624643-7	no	yes	no	0,05			(1)
			methylenebis(3-chloro-2,6-diethylaniline)						
756	40020	0110553227-0	yes	no	yes		(24)		
			bis(octylthiomethyl)-6-methylphenol						
757	95725	0110638716	yes	no	no				
			granules reaction product with citric acid, lithium salt						
758	38940	0110675226-8	yes	no	yes		(24)		
			bis(dodecylthiomethyl)-6-methylphenol						

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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759	54300	0118337	209-0	yes	no	yes	6			
			ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite							
760	83595	0119345	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	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/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-

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										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
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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										as co-monomer (max 4 %) for polyesters (PET, PBT).
765	49485	0134701220-5	dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			
766	38879	013586156-2	bis(3,4-dimethylbenzylidene)sorbitol	yes	no	no				
767	38510	0136504195-6	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	014392501-2	bis(hydrogenated tallow alkyl) oxidised	yes	no	no				Not to be used for articles in contact with fatty foods for which (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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										[^{F1} simulant D1 and/or D2] is laid down. Only to be used in: (a) polyolefins at 0,1 % (w/w) concentration and in PET at 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	2,4,6-tris(diphenyl-1,3,5-triazin-2-	yes	no	no	0,05			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			yl)-5-(hexyloxy)phenol						
771	34650	015184	lauryl)-5-(hexyloxy)phenol	no	no	5			
772	47500	015325	hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl)phosphate]	yes	no	no	5		
773	38840	015486	dicyclohexyl-2,6-naphthalene dicarboxamide	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 (2,4-dicumylphenol)
774	95270	016171	tris(tert-butylphenyl)-2-butyl-2-ethyl-1,3-propanediol phosphite	yes	no	yes	2		SML expressed as sum of phosphite, phosphate and

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									the hydrolysis product = TTBP	
775	45705	0166412478-8	cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)		
776	76723	01678830651	polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate			no			The fraction with molecular weight below 1 000 Da [F ¹ shall] not exceed 1,5 % (w/w)	
777	31542	0174254231	azelaic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters	yes	no	no			0,5 % in final product	(1)
778	71670	0178671584	penterythritol tetrakis		no	yes	0,05			

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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F⁵OJ L 83, 22.3.2012, p. 1.]

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			(2-cyano-3,3-diphenylacrylate)							
[^{F1} 779]	39815	0182121912-6	bis(methoxymethyl)fluorene	yes	no	yes	0,05			(2)]
780	81220	01922686017	[[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	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			[N'-tetrabutyl-1,3,5-triazine-2,4-diamine]						
781	95265	0227099160,57	tris(4-benzoylphenyl)benzene	yes	no	no	0,05		
782	76725	06614760	polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane			no			The fraction with molecular weight below 1 000 Da [F ¹ shall] not exceed 1 % (w/w)
783	55910	07361506	glycerides of castor-oil mono-, hydrogenated, acetates		no	no		(32)	
[F ⁶ 784	95420	0745070161,5	tris(2,2-dimethylpropanamido)benzene	yes	no	no	5]
785	24910	00001006	terephthalic acid	yes	no			(28)	

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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F⁵OJ L 83, 22.3.2012, p. 1.]

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786	14627	0000117	321-5 chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3- chlorophthalic acid	
787	14628	0000118	445-6 chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4- chlorophthalic acid	
788	21498	0002530	185-0 (methacryloxy)propyl]trimethoxysilane	no	yes	no	0,05		Only (1) to be (11) used 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-	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).	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			tetradecene (Mw: 440– 12 000)							
790	80480	009075 008245	poly- morpho- lin-1,3,5- triazine-2,4- diyl)- [(2,2,6,6- tetramethyl-4- piperidyl)imino] hexa- methylene- [(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'- 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-	yes	no	no	0,05			

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine						
792	92475	0203255383	3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid	no	yes	5		SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products	
793	94000	00001026716	triethanolamine	no	no	0,05		SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine	
[^{F8} 794	18117	000007914	glycolic acid	no	yes	no		Only to be used]]

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									for manufacture of polyglycolic acid (PGA) for (i) indirect food contact behind polyesters such as polyethylene terephthalate (PET) or polylactic acid (PLA); and (ii) direct food contact of a blend of PGA up to 3 % w/w in PET or PLA.	
795	40155	01241725, 01241726, 01241727, 01241728	yes	no	no	0,05				(2) (12)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			N,N'-diformylhexamethylenediamine						
796	72141	0018600257-4	(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	yes	no	yes	0,05		SML including the sum of its hydrolysis products
[^{F8} 797	76807	0073018205	Diethyl ester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)	I
798	92200	000642286	terephthalic acid, bis(2-ethylhexyl)ester	no	no	no	60	(32)	
[^{F6} 799	77708		polyethylene glycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									for food additives in Commission Regulation (EU) No 231/2012.	
800	94425	0000867	tributyl phosphonoacetate	yes	no	no			Only for use in PET	
801	30607	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt	yes	no	no				
802	33105	0146340	alcohols C ₁₂ -C ₁₄ secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5			(12)
803	33535	0152261	3-1 alkenes (C ₂₀ -C ₂₄) copolymer with	yes	no	no			Not to be used for articles	(13)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.]

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine					in contact with fatty foods for which [F1simulant D1 and/or D2] is laid down. Not to be used in contact with alcoholic foods.
804	80510	1010121	80473- nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised	yes	no	no		Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)

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 [F3Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5OJ L 83, 22.3.2012, p. 1.]

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			with dodecylbenzenesulfonic acid						
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
[^{F7} 807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles. Only to be used in polyethylene terephthalate (PET) 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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, 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	0882073	bis(4-propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products
809	49080	0852282	(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)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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810	68119		neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down.	
811	80077	006844	polyethylene waxes, oxidised	no	no	60			
[F8] 812	80350	0124578	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	no	no			Only to be used in plastics up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.]

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 [F3 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4 Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5 OJ L 83, 22.3.2012, p. 1.]

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813	91530	—	sulphosulphonic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts	yes	no	no	5			
814	91815	—	sulphosulphonic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts	yes	no	no	2			
815	94985	—	trimethylolpropane 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 [F ¹ simulant D1 and/or D2] is laid down	
816	45704	—	cis-1,2-cyclohexanedicarboxylic	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 [F³Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F⁴Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F⁵OJ L 83, 22.3.2012, p. 1.]

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			acid, salts							
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 %.
818	21530	—	methallyl acid, salts	no	yes	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

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.]

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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										[^{F1} simulant D1 and/or D2] 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)
823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5				
854	71943	0329238-2416	perfluoroacetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol	yes	no	no				Only to be used in concentrations up to 0,5 % w/w in the polymerisation of fluoropolymers	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups					that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles
[^{F11} 855	40560		(butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	yes	no	no		Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.
856	40563		(butadiene, styrene, methyl methacrylate, butyl acrylate)	yes	no	no		Only to be used in rigid poly(vinyl

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate						chloride) (PVC) at a maximum level of 12 % at room temperature or below.
857	66765	0037953	(ethyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % at room temperature or below.
[^{F5} [^{X1} 858	38565	0090498390-1	bis[2-(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane	yes	no	yes	0,05		SML (2)] expressed as the sum of the substance and its oxidation product 3-[(3-(3-tert-

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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								butyl-4-hydroxy-5-methylphenyl)prop-2-enoyloxy)-1,1-dimethylethyl]-9-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane in equilibrium with its para quinone methid tautomer.
[^{F3} 859			(butadienes, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]							
e	OJ L 158, 18.6.2008, p. 17.							
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.							
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]							
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]							

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									room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be >
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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									20 nm, and for at least 95 % by number it shall be > 40 nm.
860	71980	0051798	perfluoropolyethers (poly(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
861	71990	0013252	perfluoropolyethers (n-propoxy)propanoic acid]	no	no				Only to be used in the polymerisation 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.](#)

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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									fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
[^{F8} 862]	15180	0018085302-4	no diacetoxy-1-butene	no	yes	no	0,05		SML (17) including (19)] the hydrolysis product 3,4-dihydroxy-1-butene Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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[^{F11} 863	15260	000064612503	no decanediamine	yes	no	0,05		Only to be used as a co-monomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150 °C.]]
864	46330	0000056206-4	yes diamino-6-hydroxypyrimidine	no	no	5		Only to be used in rigid poly(vinyl chloride) (PVC) 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.

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									contact with non-acidic and non-alcoholic aqueous food	
[^{F7} 865	40619	0025322	0001 (0001 acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in: (a) (b)] rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w; polylactic acid (PLA) at a maximum level of 5 % w/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.									
d	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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866	40620	—	(butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 7 %	
867	40815	0040471	(butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
[^{F7} 868	53245	0009010	(butyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in: (a)] rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									(b)	w/ w; polylactic acid (PLA) at a maximum level of 5 % w/ w;
									(c)	w/ w; polyethylene terephthalate (PET) at a maximum level of 5 % w/ w.
869	66763	0027136	4158 (butyl acrylate, methyl methacrylate, styrene) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 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.

d [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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870	95500	0160535	54616 'N"- tris(2- methylcyclohexyl)-1,2,3- propane- tricarboxamide	yes	no	no	5			
[^{F12} 871		0287916	8613 acetic acid, 12- amino-, polymer with ethene, 2,5- furandione, α- hydro- ω- hydroxy- poly (oxy-1,2- ethanediyl) and 1- propene	yes	no	no			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature	(23)]

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food.
[^{F13} 872]		0006607241-6	phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	no	yes	no	0,05		To be used only as a co-monomer in polycarbonate copolymers (20)]
[^{F11} 873]	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no			Reaction] product of titanium dioxide with up to 2 % w/w surface treatment substance

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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									octyltriethoxysilane, processed at high temperatures.
[^{F5} 874	16265	0156065600-8	no dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, ω-3-dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane	yes	no	0,05	(33)	Only to be used as comonomer in siloxane modified polycarbonate. The oligomeric mixture shall be characterised by the formula $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ ($50 > n \geq 26$).]
875	80345	0058128p21612	hydroxystearic acid) stearate	yes	no	yes	5		
878	31335	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C ₃ -C ₂₂)						
879	31336	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C ₁ -C ₂₂)	yes	no	no			
[^{F6} 880]	31348		acids, fatty (C ₈ -C ₂₂), esters	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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			with pentaerythritol'						
881	25187	000301029544	29544-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for: (a) repeated use articles for long term storage at room temperature or below and hotfill; (b) single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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										component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 % and for which Table 2 of Annex III
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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										does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles.
882	25872	000241629346	no trimethylphenol	no	yes	no	0,05			
883	22074	0004457371-0	no methyl-1,5-pentanediol	no	yes	no	0,05		Only to be used in materials in contact with food at a surface to mass ratio up to 0,5 dm ² /kg	

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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884	34240	0091082	alkyl-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 [F1]simulant D1 and/or D2] 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

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 [F3Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [F4]Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5OJ L 83, 22.3.2012, p. 1.]

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									concentrations up to 1 % w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.
[^{F11} 894	93360	0016545	5548-11-01 di-propionic acid, ditetradecyl ester	no	no			(14)	
895	47060	0171090	3963-5-03 di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols	yes	no	no	0,05		Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products.

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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896	71958	0958445341-8	perfluoro-3-[(3-methoxypropoxy)propanoic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers when: — processed at temperatures higher than 280 °C for at least 10 minutes, — processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

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									and intended for repeated use articles.	
[^{F5} 902		000012844-9	benzothiazolone 1,1-dioxide, sodium salt	yes	no	no			The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU) No 231/2012 ^a .] repeated use articles.
[^{F3} 903		37486-624-	perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]	yes	no	no			Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for:] repeated and single use

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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										materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]									
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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										from 300 °C and up to 360 °C for at least 10 minutes.
923	39150	0000120	MON bis(2-hydroxyethyl)dodecanamide	yes	no	no	5		The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, [F1 shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food.	(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 [F3Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [F4Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [F5[OJ L 83, 22.3.2012, p. 1.](#)]

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924	94987		trimethylpropylamine	no	no	0,05		Only for use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products.
926	71955	0908020	perfluoro(2-ethoxyethoxy)acetic acid], ammonium salt	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes.
[^{F3} 969		24937-78	styleneyes vinyl	no	no			Only to be]

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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			acetate copolymer wax					used as a polymeric additive up to 2 % w/ w in polyolefins. The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/ kg food.	
971	25885	0002459	trifluoromethyl trimellitate	yes	no			Only to be used as a co- monomer up to 0,35 % w/w to produce modified polyesters intended to be used	(17)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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										in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158	87466 sodium hydroxide phosphate	yes	no	no				
973	22931	0019430	(93-Fluoro-1,1-butyl)ethylene	no	no	no				Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.
[^{F1} 974	74050	939402-	02-5-phosphoric acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-	yes	no	yes	5			SML expressed as the sum of the phosphite and

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

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			(1,1-dimethylpropyl)phenyl triesters					phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food.
[^{F5} 979]	79987	—	(polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer	no	no			Only to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w.
[^{F13} 988]		3634-83-	1,3-bis(isocyanatomethyl)benzene	no	yes	no	(34)	SML(T)] applies to the migration of its hydrolysis

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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								product, 1,3- benzenedimethanamine To be used only as co- monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film
[^{F3} 998			(butadienes, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross- linked, in nanoform	no	no			Only to be used as particles in non- plasticised PVC up to 10 % w/w in contact with all food types
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]							
e	OJ L 158, 18.6.2008, p. 17.							
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.							
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]							
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]							

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										at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]									
e	OJ L 158, 18.6.2008, p. 17.									
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.									
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h	[^{F5} OJ L 83, 22.3.2012, p. 1.]									

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									be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
1017		25618-5	polyglycol	no	no				To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.
[^{F12} 1031]		3238-40	tran-2,5-dicarboxylic acid	yes	no	5			Only (22) to be (23) used as a monomer in the production of polyethylene furanoate. The migration of the

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

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									oligomeric fraction of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as furan-2,5-dicarboxylic acid).
1034		3710-30-37-	37-octadiene	no	yes	no	0,05		Only to be used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

Status: Point in time view as at 14/09/2016.

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

								room temperature, including when packaged under hot-fill conditions.
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform	yes	no	no		Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}[OJ L 83, 22.3.2012, p. 1.](#)]

Status: Point in time view as at 14/09/2016.

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

								substance with FCM No 859 and/ or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
[^{F12} 1045]	119093	perfluoroacetic acid,	no	no				Only to be
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]							
e	OJ L 158, 18.6.2008, p. 17.							
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.							
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]							
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]							

Status: Point in time view as at 14/09/2016.

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-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt					used as a polymer production aid during the manufacture of fluoropolymers under high temperature conditions of at least 370 °C.
1046			zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788)	yes	no	no		Only to be used in unplasticised polymers. The restrictions and specifications specified for FCM substance No 788 shall be respected.

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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

1048		624-03-3	ethylene glycol dipalmitate	yes	no	no		(2)	Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils.	
1050			zinc oxide, nanoparticles, uncoated	yes	no	no			Only to be used in unplasticised polymers.	
1051		42774-1	N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl) isophthalamide	yes	no	no	5			
1052		1455-42	2,4,8,10-tetraoxaspiro[5,5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- ('SPG')	no	yes	no	5		Only to be used as a monomer in the production of polyesters. The migration of	(22) (23)

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 [^{F3}Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

e OJ L 158, 18.6.2008, p. 17.

f [^{F4}Infant as defined in Article 2 of Directive 2006/141/EC.

g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

h [^{F5}OJ L 83, 22.3.2012, p. 1.]

Status: Point in time view as at 14/09/2016.

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

								oligomers of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as SPG).	
1053			fatty acids, C16–18 saturated, esters with dipentaerythritol	yes	no	no		Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils]
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	[^{F3} Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]								
e	OJ L 158, 18.6.2008, p. 17.								
f	[^{F4} Infant as defined in Article 2 of Directive 2006/141/EC.								
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]								
h	[^{F5} OJ L 83, 22.3.2012, p. 1.]								

Editorial Information

- X1** Substituted by [Corrigendum to Commission Regulation \(EU\) No 1183/2012 of 30 November 2012 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Official Journal of the European Union L 338 of 12 December 2012\).](#)

Status: Point in time view as at 14/09/2016.

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

Textual Amendments

- F3** Inserted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F4** Inserted by Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (Text with EEA relevance).
- F5** Inserted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F6** Substituted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F7** Substituted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F8** Substituted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F9** Substituted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F10** Deleted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F11** Inserted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F12** Inserted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F13** Inserted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

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.

Status: Point in time view as at 14/09/2016.

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

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
[^{F1} 2	89 227 263 1048	30	expressed as ethyleneglycol]
3	234 248	30	expressed as maleic acid
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	0,006	expressed as tin

Status: Point in time view as at 14/09/2016.

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

	736		
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
[^{F8} 14	294 368 894]	5	expressed as the sum of the substances and their oxidation products
[^{F6} 15	98 196 344	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	6	expressed as acrylic acid

Status: Point in time view as at 14/09/2016.

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

	176 218 323 325 365 371 380 425 446 448 456 636		
23	150 156 181 183 184 355 370 374 439 440 447 457 482	6	expressed as methacrylic acid
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

Status: Point in time view as at 14/09/2016.

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

[^{F6} 30	254 344 672	5	expressed as 1,4-butenediol]
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815	60	expressed as the sum of the substances
[^{F5} 33	180 874	ND	expressed as eugenol]
[^{F13} 34	421 988	0,05	Expressed as 1,3-benzenedimethanamine]

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.

Status: Point in time view as at 14/09/2016.

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)	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.
[^{F7} (4)]	Compliance testing when there is a fat contact [^{F1} shall] be performed using saturated fatty food simulants as simulant D2.]
(5)	Compliance testing when there is a fat contact [^{F1} shall] 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.
(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.

Status: Point in time view as at 14/09/2016.

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

(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
[^{F11} (18)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)
(19)	There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers]
[^{F13} (20)	The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary]
[^{F3} (21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.]
[^{F12} (22)	When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1.
(23)	When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.]

4. Detailed specification on substances

Table 4 on detailed specifications on substances contains the following information

Status: Point in time view as at 14/09/2016.

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

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.

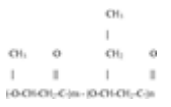
Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

(1)	(2)	
FCM substance No	Detailed specification on the substance	
744	Definition	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
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)

Status: Point in time view as at 14/09/2016.

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

	CAS number	0080181-31-3
	Structural formula	 <p>where n/(m + n) greater than 0 and less or equal to 0,25</p>
	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-hydroxypentanoate) 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 14/09/2016.

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.

- [^{F1}2. Primary aromatic amines which are not listed in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant in accordance with Article 11(4). The detection limit referred to in the second subparagraph of Article 11(4) 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.

[^{F1}TABLE 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E]

2. General assignment of food simulants to foods

Status: Point in time view as at 14/09/2016.

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

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.

[^{F13} **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 to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be 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

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 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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 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						

Status: Point in time view as at 14/09/2016.

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

01.01	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, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract		X(*)	X			
	B. cloudy drinks: juices and nectars and soft drinks		X(*)		X		

Status: Point in time view as at 14/09/2016.

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

	containing fruit pulp, musts containing fruit pulp, liquid chocolate						
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		
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

Status: Point in time view as at 14/09/2016.

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

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 the surface					X/3	
	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						

Status: Point in time view as at 14/09/2016.

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

	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 the surface					X/3	
	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						X

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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)

		or powder					
	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:						
	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,	X(*)	X			

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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)

		compote, and similar products)					
	C.	Fruit preserved in a liquid medium:					
	I.	In an oily medium				X	
	II.	In an alcoholic medium			X		
04.03		Nuts (peanuts, 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					

Status: Point in time view as at 14/09/2016.

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

	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 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					X	

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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)

		oily medium					
	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	
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:					

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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)

	I.	In an oily medium	X				X	
	II.	In an aqueous medium	X(*)	X				
06.02		Crustaceans and molluscs (including oysters, mussels, snails)						
	A.	Fresh within the shell						
	B.	Shell removed, processed, preserved or cooked with the shell						
	I.	In an oily medium	X				X	
	II.	In an aqueous medium	X(*)	X				
06.03		Meat of all zoological species (including poultry and game):						

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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)

	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(**)	
	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						

Status: Point in time view as at 14/09/2016.

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.	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 or partly skimmed			X		
	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		

Status: Point in time view as at 14/09/2016.

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

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(**)	
	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		

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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)

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, 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					

Status: Point in time view as at 14/09/2016.

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

		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 creams and other oil/ water mixtures e.g. coconut based sauces	X(*)			X	
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing						

Status: Point in time view as at 14/09/2016.

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

	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
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

Status: Point in time view as at 14/09/2016.

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. 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 and others						X
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,					X	

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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)

curry paste							
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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.

[^{F125} **General derogation to the assignment of food simulants**

By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.]

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;

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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)

- (4) the date of the declaration;
- (5) [F¹confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of 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

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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)

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.

[^{F1}1.4. **Account of substances originating from other sources**

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit.]

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

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

[^{F1}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.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

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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)

- (i) 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;
- (ii) if the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.]

TABLE 1

[^{F1}Selection of test time]

Contact time in worst foreseeable use	[^{F1} Time to be selected for testing]
$t \leq 5$ 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

[^{F1}TABLE 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
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)

$T \leq 5 \text{ }^{\circ}\text{C}$	5 °C
$5 \text{ }^{\circ}\text{C} < T \leq 20 \text{ }^{\circ}\text{C}$	20 °C
$20 \text{ }^{\circ}\text{C} < T \leq 40 \text{ }^{\circ}\text{C}$	40 °C
$40 \text{ }^{\circ}\text{C} < T \leq 70 \text{ }^{\circ}\text{C}$	70 °C
$70 \text{ }^{\circ}\text{C} < T \leq 100 \text{ }^{\circ}\text{C}$	100 °C or reflux temperature
$100 \text{ }^{\circ}\text{C} < T \leq 121 \text{ }^{\circ}\text{C}$	121 °C ^a
$121 \text{ }^{\circ}\text{C} < T \leq 130 \text{ }^{\circ}\text{C}$	130 °C ^a
$130 \text{ }^{\circ}\text{C} < T \leq 150 \text{ }^{\circ}\text{C}$	150 °C ^a
$150 \text{ }^{\circ}\text{C} < T < 175 \text{ }^{\circ}\text{C}$	175 °C ^a
$175 \text{ }^{\circ}\text{C} < T \leq 200 \text{ }^{\circ}\text{C}$	200 °C ^a
$T > 200 \text{ }^{\circ}\text{C}$	225 °C ^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.]

[^F12.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C⁽¹⁾.

- (a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to $70 \text{ }^{\circ}\text{C} \leq T \leq 100 \text{ }^{\circ}\text{C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to $70 \text{ }^{\circ}\text{C} \leq T \leq 100 \text{ }^{\circ}\text{C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to $70 \text{ }^{\circ}\text{C} \leq T \leq 100 \text{ }^{\circ}\text{C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.
- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$$t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$$

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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)

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 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).

T2 is the testing temperature in Kelvin.]

2.1.5. Specific conditions for combinations of contact times and temperature

[^{F1}If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall 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.

[^{F1}The material or article shall respect the specific migration limit already in the first test for substances that are prohibited from migrating or from being released in detectable quantities under Article 11(4).]

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

[^{F1}To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.]

2.2.1. Replacing specific migration by overall migration

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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)

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

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.

[^{F1}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 in a way that must never underestimate real levels of migration.]

[^{F1}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 result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.]

[^{F12}2.2.5. *Single test for successive combinations of time and temperature*

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16.]

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.

[^{F1}TABLE 3

Standardised conditions for testing the overall migration

Status: Point in time view as at 14/09/2016.

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

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at contact temperature in [°C] for testing	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 when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum of $t = 120/2^{((T-70)/10)}$ minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C	High temperature applications for all types of food 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 at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.]

[^{F1}Test OM7 also covers food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents the worst case conditions for food simulant D2 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 Section 3.2.

Test OM6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B, C and D1 in contact with non-polyolefins.

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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)

Test OM5 covers also food contact conditions described for OM1, OM2, OM3, and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM2 covers also food contact conditions described for OM1 and OM3.]

[^F13.2. **Substitute overall migration tests for tests with food simulant D2**

If it is not technically feasible to perform one or more of the tests OM1 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2 the test can be replaced by either test OM8 or test OM9 as appropriate given the intended or foreseeable use. Both tests involve testing at two test conditions for which a new test sample shall be used for each test. The test condition that results in the highest overall migration shall be used to establish compliance with this Regulation.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
OM8	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
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6]

[^F13.3. **Verification of compliance**

3.3.1. *Single use articles and materials*

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

3.3.2. *Repeated use articles and materials*

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to test the same sample three times, such as when testing in oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The difference between

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the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, it shall not be higher than the first result and the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration does not increase in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient.]

3.4. Screening approaches

[^{F1}To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as 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.

[^{F1}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 result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.]

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

[^{F1}The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.]

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[^{F12}When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.]

F²4.2. Correction of migration into food simulant D2

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F²4.3. Combination of correction factors 4.1 and 4.2.

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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
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

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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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- (1) [^{F1}When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.]

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Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food](#) (Text with EEA relevance).

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