

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)

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

ANNEX I **U.K.**

Substances

1. ^{F1}... List of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids **U.K.**

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).

[^{F2}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

- F2** 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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I. (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.

F3
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Textual Amendments

F3 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] (yes/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, linear, primary (C ₄ -C ₂₂)	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)

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

			(60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate						
5	25360	—	trialkyl (C ₆ -C ₁₅) acetic acid, 2,3-epoxypropyl ester	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	no	0,05		(1)
7	30370	—	acetylates acetic acid, salts	no	no				
8	30401	—	acetylates 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	yes	no	no			

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

			(branched fatty acids at naturally occurring levels are included)							
10	30612	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no				
11	30960	—	acids, aliphatic, monocarboxylic (C ₆ -C ₂₂), esters with polyglycerol	yes	no	no				
12	31328	—	acids, fatty, from animal or vegetable food fats and oils	yes	no	no				
13	33120	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₂₄)	yes	no	no				
14	33801	—	n-alkyl(C ₁₀ -	yes	no	no	30			

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

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

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

			and diglycerides						
23	43515	—	chlorides of choline esters of coconut oil fatty acids	yes	no	no	0,9		(1)
24	45280	—	cotton fibers	yes	no	no			
25	45440	—	cresols, butylated, styrenated	yes	no	no	12		
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(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)	yes	no	no	5		
27	48960	—	9,10-dihydroxy stearic	yes	no	no	5		

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			acid and its oligomers							
28	50160	—	di-n-octyltin bis(n-alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	yes	no	no		(10)		
29	50360	—	di-n-octyltin bis(ethyl maleate)	yes	no	no		(10)		
30	50560	—	di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	yes	no	no		(10)		
31	50800	—	di-n-octyltin dimaleate, esterified	yes	no	no		(10)		
32	50880	—	di-n-octyltin dimaleate, polymers (n = 2-4)	yes	no	no		(10)		
33	51120	—	di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	yes	no	no		(10)		
34	54270	—	ethylhydroxyethylcellulose	yes	no	no				
35	54280	—	ethylhydroxypropylcellulose	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and	yes	no	no				

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

			oils, hydrogenated, from animal or vegetable food sources							
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 acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C ₁₆ - C ₁₈)	yes	no	no				
42	56487	—	glycerol, esters	yes	no	no				

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

			with butyric acid						
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 linoleic acid	yes	no	no			
47	56520	—	glycerol esters with myristic acid	yes	no	no			
48	56535	—	glycerol esters with nonanoic acid	yes	no	no			
49	56540	—	glycerol esters with oleic acid	yes	no	no			
50	56550	—	glycerol esters with palmitic acid	yes	no	no			
51	56570	—	glycerol esters with	yes	no	no			

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

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

60	58300	—	glycine, salts	yes	no	no				
62	64500	—	lysine, salts	yes	no	no				
63	65440	—	manganese pyrophosphite	yes	no	no				
64	66695	—	methylcellulose	yes	no	no				
65	67155	—	mixture of 4-(2-benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxazolyl)stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene	yes	no	no				Not more than 0,05 % (w/w) (quantity of substance used/ quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %): (23-27 %): (13-17 %).
66	67600	—	mono-n-octyltin tris(alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	yes	no	no		(11)		
67	67840	—	montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol	yes	no	no				

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			and/or with glycerol						
68	73160	—	phosphoric acid, mono- and di- n-alkyl (C ₁₆ and C ₁₈) esters	yes	no	yes	0,05		
69	74400	—	phosphoric acid, tris(nonyl- and/or dinonylphenyl) ester	yes	no	yes	30		
70	76463	—	polyacrylic acid, salts	yes	no	no	(22)		
71	76730	—	polydimethylsiloxane, γ- hydroxypropylated	yes	no	no	6		
72	76815	—	polyesters of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C ₁₂ - C ₂₂ fatty acids	yes	no	no	(32)	The fraction with molecular weight below 1 000 Da [^{F2} shall] not exceed 5 % (w/w)	
73	76866	—	polyesters of 1,2- propanediol and/ or 1,3- and/ or 1,4- butanediol	yes	no	yes	(31) (32)		

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

			and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol					
74	77440	—	polyethyl- ene glycol diricinolate	yes	42			
75	77702	—	polyethyl- ene glycol esters of aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates	no				
76	77732	—	polyethyl- ene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-	no	no	0,05		Only for use in PET

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

			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	—	powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	no	no			
81	83320	—	propylhydroxyethylcellulose	no				
82	83325	—	propylhydroxyethylcellulose	no				

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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		
86	86000	—	silicic acid, silylated	yes	no	no		
[^{F2} 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.]

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88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no		(2)		
90	92195	—	taurine, salts	yes	no	no				
91	92320	—	tetradecyl polyethyleneglycol ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclic bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05			Not to be used for articles in contact with fatty foods for which [F2 simulant D1 and/ or D2] is laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less

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Commission Regulation (EU) No 10/2011, ANNEX I. (See end of Document for details)

									than 2,5 cSt ($2,5 \times 10^{-6}$ 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 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).

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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 ($8,5 \times 10^{-6}$ m ² /s). Content of 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

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107	25960	000005713-6	urea	no	yes	no			
108	24880	000005750-0	stearic acid	no	yes	no			
109	23740	000005715-6	propanediol	yes	yes	no			
	81840								
110	93520	000005902-9 00101914	dephenol	yes	no	no			
111	53600	000006000-4	benzoinic acid	yes	no	no			
112	64015	000006013-0	lactic acid	yes	no	no			
113	16780	000006417-5	ellagic acid	yes	yes	no			
	52800								
114	55040	000006418-6	formic acid	yes	no	no			
115	10090	000006419-7	acetic acid	yes	yes	no			
	30000								
116	13090	000006585-0	benzoic acid	yes	yes	no			
	37600								
117	21550	000006756-1	ethanol	no	yes	no			
118	23830	000006726-0	propanol	yes	yes	no			
	81882								
119	30295	000006764-0	ethane	yes	no	no			
120	49540	000006768-0	ethyl sulphoxide	yes	no	no			
121	24270	000006957-7	salicylic acid	yes	yes	no			
	84640								
122	23800	000007112-3	propanol	no	yes	no			
123	13840	000007113-6	butanol	no	yes	no			
124	22870	000007114-1	pentanol	no	yes	no			
125	16950	000007485-1	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

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

128	10060	000007550740	50740	aldehyde	yes	no		(1)		
129	17020	000007552110	52110	ethylbenzene oxide	yes	no	ND		1 mg/kg in final product	(10)
130	26110	000007553540	53540	vinylidene chloride	yes	no	ND			(1)
131	48460	00000755137-6	5137-6	yes difluoroethane	no	no				
132	26140	000007553870	53870	vinylidene fluoride	yes	no	5			
133	14380	00000755446-6	5446-6	nylino chloride	yes	no	ND		1 mg/kg in final product	(10)
	23155									
134	43680	000007554560	54560	chlorodifluoromethane	no	no	6		Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	000007555690	55690	propylene oxide	yes	no	ND		1 mg/kg in final product	
136	41680	000007622220	622220	yes	no	no				(3)
137	66580	0000077262-3	7262-3	yes methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	no	yes		(5)		
138	93760	000007740700	740700	butyl acetyl citrate	yes	no	no			(32)
139	14680	000007792100	792100	acid	yes	yes	no			
	44160									
140	44640	000007793100	793100	acid, triethyl ester	yes	no	no			(32)

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

141	13380	0000077199-6	1,3-trimethylolpropane	yes	yes	no	6		
	25600								
	94960								
142	26305	0000078084-0	triethoxysilanes	no	no	0,05		Only to be used as a surface treatment agent	[F ⁹ (1)]
143	62450	0000078178-4	isopentane	yes	no	no			
144	19243	0000078279-5	methyl-1,3-butadiene	no	yes	no	ND		1 mg/kg in final product
	21640								
145	10630	0000079006-1	amide	yes	no	ND			
146	23890	0000079009-1	acetic acid	yes	yes	no			
	82000								
147	10690	0000079021-1	acetic acid	no	yes	no		(22)	
148	14650	0000079118-9	trifluoroethylene	no	no	no	ND		(1)
149	19990	0000079130-0	acrylamide	yes	no	no	ND		
150	20020	0000079141-1	acrylic acid	yes	no	no		(23)	
[F ⁶ 151]	13480	0000080205-7	bis(4-hydroxyphenyl)propane	no	yes	no	0,05		Not to be used for the manufacture of polycarbonate infant ^f feeding bottles ^g .
	13607]								Not to be used for the manufacture of polycarbonate drinking cups or

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									bottles which, due to their spill proof characteristics, are intended for infants ⁱ and young children ^j .	
152	15610	0000080407-9	no dichlorodiphenyl sulphone	yes	no	0,05				
153	15267	0000080408-0	no diaminodiphenyl sulphone	yes	no	5				
154	13617 16090	0000080409-1	no dihydroxydiphenyl sulphone	yes	no	0,05				
155	23470	0000080405-8	no pinene	yes	no					
156	21130	0000080406-1	no methacrylic acid, methyl ester	yes	no		(23)			
157	74880	0000080411-2	yes phthalic acid, dibutyl ester	yes	no	0,3	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in	

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										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 articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-

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										based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
160	84800	0000087	salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
[^{F10} 161	92160	000087	(4)-tartaric acid	yes	no	no]				
162	65520	0000087	nitro	yes	no	no				
163	66400	0000088	2,2'-4-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088	268-6 aminobenzamide	yes	no	no	0,05			Only for use in PET for water and beverages

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

165	23200	0000088	99-3 phthalic acid	yes	yes	no				
	74480									
166	24057	0000089	32-7 phthalic anhydride	yes	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	0000091	1276-9 diamino-6- phenyl-1,3,5- triazine	no	yes	no	5			[F ⁹ (1)]
	15310									
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, propyl ester	yes	no	no				
174	14740	0000095	5648-7 cresol	no	yes	no				
175	20050	0000096	6051-9 acrylic acid, allyl ester	no	yes	no	0,05			

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

176	11710	000009633	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	000009645	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	
178	92800	000009649	2,2,4,4-tetrakis(6-tert-butyl-3-methylphenol)propane	yes	no	yes	0,48			
179	48800	000009722	4,4'-dihydroxy-5,5'-dichlorodiphenylmethane	yes	no	yes	12			
[^{FI} 180]	17160	000009753	phenol	no	yes	no		(33)		
181	20890	000009762	acrylic acid, ethyl ester	no	yes	no		(23)		
182	19270	000009765	acrylic acid	no	yes	no				
183	21010	000009786	acrylic acid, isobutyl ester	no	yes	no		(23)		
184	20110	000009788	acrylic acid,	no	yes	no		(23)		

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

			butyl ester						
185	20440	0000097	9015-9015- acrylic acid, diester with ethyleneglycol	yes	no	0,05			
186	14020	0000098	4514-4514- butylphenol	no	yes	no	0,05		
187	22210	0000098	883-9883-9 methylstyrene	no	yes	no	0,05		
188	19180	0000099	1508-1508- phthalic acid dichloride	yes	no		(27)		
189	60200	0000099	476-3476-3 hydroxybenzoic acid, methyl ester	yes	no	no			
190	18880	0000099	996-7996-7 hydroxybenzoic acid	no	yes	no			
191	24940	0000100	1009-1009- phthalic acid dichloride	yes	no		(28)		
192	23187	—	phthalic acid	no	yes	no		(28)	
193	24610	0000100	42-42- styrene	no	yes	no			
194	13150	0000100	51-51- benzyl alcohol	no	yes	no			
195	37360	0000100	52-52- benzaldehyde	no	no	no			(3)
196	18670	0000100	97-97- hexamethylenetetramine	no	no	no		(15)	
	59280								
197	20260	0000101	419-419- methacrylic acid, cyclohexyl ester	yes	no	0,05			
198	16630	0000101	468-468- methylenebis(4,4'-diisocyanate)	no	no	no		(17)	1 mg/kg in final product expressed as (10)

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

									isocyanate moiety	
199	24073	000010200010	1,3-bis(4-hydroxyphenyl)propane diglycidyl ether	yes	no	ND			Not to be used for articles in contact with fatty foods for which [F ² simulant D1 and/or D2] is laid down. For indirect food contact only, behind a PET layer.	(8)
200	51680	000010200010	2,2-bis[4-(4-phenylthio)phenyl]propane	yes	no	yes	3			
201	16540	000010200010	2,2-bis(4-phenyl)propane carbonate	no	yes	no	0,05			
202	23070	000010200010	2,2-bis(4-phenylenedioxy)propane diacetic acid	no	yes	no	0,05			[F ⁹ (1)]
203	13323	000010200010	1,4-bis(2-hydroxyethoxy)benzene	no	yes	no	0,05			
204	25180 92640	000010200010	2,2-bis[4-(2-hydroxypropyl)phenyl]propane ethylenediamine	yes	yes	no				
205	25385	000010200010	2,2-bis(4-phenyl)propane ethylenediamine	yes	no				40 mg/kg hydrogel at a ratio of 1 kg food	

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

									to a maximum of 1,5 grams of hydrogel. Only to be used in hydrogels intended for non-direct food contact use.	
206	11500	0000103	3417-1 acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05			
207	31920	0000103	3417-2 acrylic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)		(2)
208	18898	0000103	3904 2-(4-hydroxyphenyl) acetamide	no	yes	no	0,05			
209	17050	0000104	276-7 ethyl-1-hexanol	no	yes	no	30			
210	13390 14880	0000105	408-8 bis(hydroxymethyl)cyclohexane	no	yes	no				
211	23920	0000105	384 acrylic acid, vinyl ester	no	yes	no		(1)		
212	14200 41840	0000105	602 ε-caprolactam	no	yes	no		(4)		
213	82400	0000105	162-4 propyleneglycol dioleate	yes	no	no				

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

214	61840	0000106124-9	hydroxystearic acid	yes	no	no				
215	14170	0000106317-0	butyric anhydride	no	yes	no				
216	14770	000010644-5	cresol	no	yes	no				
217	15565	000010644-7	dichlorobenzene	no	yes	no	12			
218	11590	000010663-8	acetic acid, isobutyl ester	no	yes	no		(22)		
219	14570	000010689-8	chloroethanol	yes	no	no	ND		1 mg/ kg in final product	(10)
	16750									
220	20590	000010691-2	acrylic acid, 2,3-epoxypropyl ester	yes	no	no	0,02		(10)	
221	40570	000010697-8	toluene	yes	no	no				
222	13870	0000106498-9	butene	no	yes	no				
223	13630	000010699-0	benzidine	no	yes	no	ND		1 mg/ kg in final product	
224	13900	0000107291-7	butene	no	yes	no				
225	12100	000010731-6	acrylonitrile	yes	no	no	ND			
226	15272	000010715-5	ethylenediamine	yes	no	no	12			
	16960									
227	16990	000010727-4	ethylene glycol	yes	no	no		(2)		
	53650									
228	13690	0000107183-0	butanediol	no	yes	no				
229	14140	0000107192-6	butyric acid	no	yes	no				
230	16150	000010840-1	methylethanolamine	yes	no	no	18			

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

231	10120	000010800514	acetic acid, vinyl ester	no	yes	no	12		
232	10150	00001082417	acetic anhydride	yes	yes	no			
	30280								
233	24850	00001083105	acetic anhydride	no	yes	no			
234	19960	00001083166	maleic anhydride	no	yes	no		(3)	
235	14710	00001084794	4-cresol	no	yes	no			
[^{F12} 236	23050	00001084452	4,4'-oxydianiline	no	yes	no	ND		(28)]
237	15910	00001084453	1,4-dihydroxybenzene	no	yes	no	2,4		
	24072								
238	18070	00001085541	glutaric anhydride	no	yes	no			
[^{F13} 239	19975	00001082746	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5		
	25420								
	93720]								
240	45760	00001089118	hexylamine	no	yes	no			
[^{F10} 241	22960	00001089521	phenol	no	yes	no	3]		
242	85360	00001094543	sebacic acid, dibutyl ester	yes	no	no		(32)	
243	19060	00001095535	isobutyl vinyl ether	no	yes	no	0,05		(10)
244	71720	00001096610	pentane	yes	no	no			
245	22900	00001094671	1-pentene	no	yes	no	5		
246	25150	00001094994	2-furanmethanol	yes	yes	no	0,6		
247	24820	00001101566	succinic acid	yes	yes	no			
	90960								
248	19540	00001101647	maleic acid	yes	yes	no		(3)	
	64800								

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

249	17290	0000110117-8	Fumaric acid	yes	yes	no			
	55120								
250	53520	0000110130-5	N,N'-ethylenebisstearamide	yes	no	no			
251	53360	0000110131-6	N,N'-ethylenebisoleamide	yes	no	no			
252	87200	0000110140-1	Sebacic acid	yes	no	no			
253	15250	0000110160-1	1,4-diaminobutane	no	yes	no			
254	13720	0000110163-4	1,4-butanediol	yes	yes	no		(30)	
	40580								
255	25900	0000110183-3	Hexane	no	yes	no	5		
256	18010	0000110194-9	Tartaric acid	yes	yes	no			
	55680								
I ^{F11} 257	13550	0000110198-5	1,3-bis(2-hydroxyethyl)glycol	yes	yes	no			
	16660	0025265-71-8							
	51760								
258	70480	0000111106-8	Phthalic acid, butyl ester	yes	no	no			
259	58720	0000111144-8	Heptanoic acid	yes	no	no			
260	24280	0000111152-6	Sebacic acid	no	yes	no			
261	15790	0000111400-0	1,4-bis(2-hydroxyethyl)guanidine	yes	yes	no	5		
262	35284	0000111412-1	N-(2-aminoethyl)ethanolamine	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which I ^{F2} simulant D1 and/

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

									or D2] is laid down. For indirect food contact only, behind a PET layer.
263	13326	0000111466-1	ethylene glycol	yes	no		(2)		
	15760								
	47680								
264	22660	0000111466-0	octene	no	yes	no	15		
265	22600	0000111487-5	octanol	no	yes	no			
266	25510	0000112427-6	ethylene glycol	yes	no				
	94320								
267	15100	0000112430-1	decanol	no	yes	no			
268	16704	0000112441-4	dodecene	no	yes	no	0,05		
269	25090	0000112407-7	ethylene glycol	yes	no				
	92350								
270	22763	0000112801-8	acid	yes	yes	no			
	69040								
271	52720	0000112841-5	amide	yes	no	no			
272	37040	0000112856-6	benzoic acid	yes	no	no			
273	52730	0000112867-7	acid	yes	no	no			
274	22570	0000112909-9	decyl isocyanate	no	yes	no	(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115007-7	polyene	no	yes	no			

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

276	19000	00001155	isobutene	no	yes	no				
277	18280	00001155	hexachloroendomethylene tetrahydrophthalic anhydride	no	yes	no	ND			
278	18250	00001155	hexachloroendomethylene tetrahydrophthalic acid	no	yes	no	ND			
279	22840	00001155	pentacerythritol	yes	yes	no				
	71600									
280	73720	00001155	phosphoric acid, trichloroethyl ester	yes	no	no	ND			
281	25120	00001164	hexafluoromethylene	no	yes	no	0,05			
282	18430	00001164	hexafluoropropylene	no	yes	no	ND			
283	74640	00001179	phthalic acid, bis(2-ethylhexyl) ester	yes	no	no	1,5	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in concentrations up to 0,1 % in the final product.
284	84880	00001195	salicic acid, methyl ester	yes	no	no	30			
285	66480	00001192	4,4'-methylene bis(4-	yes	no	yes		(13)		

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

			methyl-6-tert-butylphenol)						
286	38240	0000119	benzophenone	no	yes	0,6			
287	60160	0000120	447-8 hydroxybenzoic acid, ethyl ester	yes	no	no			
288	24970	0000120	610-11 terephthalic acid, dimethyl ester	yes	no				
289	15880	0000120	480-9 dihydroxybenzene	no	yes	no	6		
	24051								
290	55360	0000121	710-10 gallic acid, propyl ester	yes	no	no	(20)		
291	19150	0000121	905-11 isophthalic acid	yes	no		(27)		
292	94560	0000122	410-3 propylamine	yes	no	5			
293	23175	0000122	510-2 phosphorus acid, triethyl ester	yes	no	ND		1 mg/kg in final product	(1)
294	93120	0000123	420-11 dodecyl propionic acid, didodecyl ester	yes	no	yes	(14)		
295	15940	0000123	414-9 dihydroxybenzene	yes	yes	no	0,6		
	18867								
	48620								
296	23860	0000123	380-6 propanaldehyde	yes	no				
297	23950	0000123	600-6 phosponic anhydride	no	yes	no			
298	14110	0000123	712-8 benzaldehyde	yes	no				
299	63840	0000123	760-11 dicyclic acid	yes	no	no			
300	30045	0000123	861-4 acetic acid, butyl ester	yes	no	no			

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

301	89120	0000123805-5	sebacic acid, butyl ester	yes	no	no			
302	12820	0000123829-6	azelaic acid	no	yes	no			
303	12130	0000124044-9	adipic acid	yes	yes	no			
	31730								
304	14320	0000124072-2	fthalic acid	yes	yes	no			
	41960								
305	15274	0000124094-4	hexamethylenediamine	yes	no	no	2,4		
	18460								
306	88960	0000124266-5	urea	yes	no	no			
307	42160	0000124280-0	carbon dioxide	yes	no	no			
308	91200	0000126313-6	isobutyrate acetate	yes	no	no			
309	91360	0000126347-7	octaacetate	yes	no	no			
310	16390	0000126370-7	dimethyl-1,3-propanediol	no	yes	no	0,05		
	22437								
311	16480	0000126558-9	pentaerythritol	yes	yes	no			
	51200								
312	21490	0000126608-5	acrylonitrile	yes	yes	no	ND		
313	16650	0000127463-9	phenylsulphone	yes	yes	no	3		
	51570								
314	23500	0000127991-3	pinene	no	yes	no			
315	46640	0000128237-0	tert-butyl-p-cresol	yes	no	no	3		
316	23230	0000131719-1	phthalic acid, diallyl ester	no	yes	no	ND		

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

317	48880	000013	1253-3 dihydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
318	48640	000013	1254-6 dihydroxybenzophenone	yes	no	no		(8)		
319	61360	000013	1257-7 hydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
320	37680	000013	660-7 benzoic acid, butyl ester	yes	no	no				
321	36080	000013	766-6 acetyl palmitate	yes	no	no				
322	63040	000013	821-7 lactic acid, butyl ester	yes	no	no				
323	11470	000014	088-5 fatty acid, ethyl ester	no	yes	no		(22)		
324	83700	000014	121-0 oleic acid	yes	no	yes	42			
325	10780	000014	132-1 lactic acid, n-butyl ester	no	yes	no		(22)		
326	12763 35170	000014	1243-5 aminoethanol	yes	yes	no	0,05			Not to be used for articles in contact with fatty foods for which [F ² simulant D1 and/or D2] is laid down.

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

										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	000014262-0	lactic acid	yes	no	no				
330	19470 63280	000014310-7	lactic acid	yes	yes	no				
331	22480	000014310-8	nonanol	no	yes	no				
332	69760	000014328-2	alcohol	yes	no	no				
333	22775 69920	000014462-7	lactic acid	yes	yes	no	6			
334	17005	000015164-4	benzidine	yes	no	no	ND			
335	68960	000030102-0	amide	yes	no	no				
336	15095 45940	000033448-5	decanoic acid	yes	yes	no				
337	15820	000034542-6	difluorobenzophenone	no	yes	no	0,05			
338	71020	000037340-6	lactic acid	yes	no	no				
339	86160	000040951-2	silicon carbide	yes	no	no				
[^{F14} 340	47440	000046158-5	diisocyanate	no	no	no	60]			
341	13180 22550	000049866-8	[2,2,1]hept-2-ene	no	no	no	0,05			
342	14260	000050244-3	lactone	yes	no	no		(29)		
343	23770	000050413-2	propanediol	no	yes	no	0,05			

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

F ¹⁰ 344	13810	0000505165-7	butanediol formal	no	yes	no	0,05	15 30		(21)
	21821]									
345	35840	0000506309-1	acetic acid	yes	no	no				
346	10030	0000514100-1	acetic acid	no	yes	no				
347	13050	0000528419-1	lactic acid	no	yes	no		(21)		
	25540									
348	22350	0000544163-8	fatty acid	yes	yes	no				
	67891									
349	25550	0000552110-7	lactic anhydride	no	yes	no		(21)		
350	63920	0000557159-5	lactic acid	yes	no	no				
351	21730	0000563345-1	methyl-1-butene	no	yes	no	ND		Only to be used in polypropylene	(1)
352	16360	0000576226-1	dimethylphenol	no	yes	no	0,05			
353	42480	0000584018-8	acetic acid, rubidium salt	yes	no	no	12			
354	25210	0000584284-9	toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
355	20170	0000585031-9	acrylic acid, tert-butyl ester	yes	yes	no		(23)		
356	18820	0000592141-6	hexene	no	yes	no	3			
357	13932	0000598332-3	buten-2-ol	no	yes	no	ND		Only to be used	(1)

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

									as a co-monomer for the preparation of polymeric additive
358	14841	0000599464-4	no cumylphenol	yes	no	0,05			
359	15970 48720	000061499-4	yes dihydroxybenzophenone	yes	no		(8)		
360	57920	000062067-7	yes glycerol triheptanoate	yes	no				
361	18700	000062911-8	no hexanediol	yes	no	0,05			
362	14350	000063088-0	no carbon monoxide	yes	no				
363	16450	000064610-0	no dioxolane	yes	no	5			
I ^{F10} 364	15404	0000652167-3,6-	no dianhydrosorbitol	yes	no	5		Only to be used as: (a) (b)	a co-monomer in poly(ethylene-co-isosorbide terephthalate); a co-monomer at levels of up to 40 mole % of the diol component in

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

									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	12-11 acetic acid, isopropyl ester	no	yes	no		(22)	
366	22150	0000691	1437-2 methyl-1-pentene	no	yes	no	0,05		
367	16697	0000693	123-2 dodecanedioic acid	no	yes	no			
368	93280	0000693	116-7 propionic acid, dioctadecyl ester	no	yes	no		(14)	

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

369	12761	0000693127-2	aminododecanoic acid	no	yes	no	0,05			
370	21460	00007609310	acrylic anhydride	yes	yes	no		(23)		
371	11510 11830	0000818611	acrylic acid, monoester with ethyleneglycol	no	yes	no		(22)		
372	18640	0000822060	hexamethylene diisocyanate	yes	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	0000840266-3	naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	00008687710	acrylic acid, monoester with ethyleneglycol	yes	yes	no		(23)		
375	15130	0000872105-9	decene	no	yes	no	0,05			
[^{F13} 376	66905	0000872150-4	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	

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

										treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles.
378	21970	0000923	302-4 methylolmethacrylamide	no	yes	no	0,05			
379	21940	0000924	442-5 methylolacrylamide	no	yes	no	ND			
380	11980	0000925	66-11 acetic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931	814-01 octane	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 urea	yes	no	no	5			
383	72160	0000948	265-2 phenylindole	yes	no	yes	15			
384	40000	0000991	1284-4 bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			

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

385	11530	0000999	acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).	(1)
386	55280	0001034	oleic acid, octyl ester	yes	no	no		(20)		
387	26155	0001072	1463-5 vinylimidazole	no	yes	no	0,05			[F ⁹ (1)]
388	25080	0001120	1436-1 tetradecene	no	yes	no	0,05			
389	22360	0001141	236-4 naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	0001166	5115 oleic acid, dodecyl ester	yes	no	no		(20)		
[F ² 391]	22932	0001187	2335 perfluoromethyl perfluorovinyl ether	yes	no	no	0,05		Only to be used in:	

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

									— —	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-ethylhexyl ester	no	yes	2,4				
393	37280	0001302	2,2,4,4-tetrahydroxy	yes	no	no				
394	41280	0001305	60-100 hydroxide	yes	no	no				
395	41520	0001305	78-80 oxide	yes	no	no				
396	64640	0001309	42-80 hydroxide	yes	no	no				
397	64720	0001309	42-80 oxide	yes	no	no				
[^{F12} 398	35760	0001309	44-100 trioxide	yes	no	no				(6)]
399	81600	0001310	58-300 hydroxide	yes	no	no				

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

400	86720	0001310571-2	zinc hydroxide	yes	no	no			
401	24475	0001313821-2	barium sulphide	no	yes	no			
402	96240	0001314211-2	zinc oxide	yes	no	no			
403	96320	0001314281-3	barium sulphide	yes	no	no			
404	67200	0001317331-5	polybenzenedisulphide	yes	no	no			
405	16690	0001321741-0	divinylbenzene	yes	no	no	ND		SML (1) expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.
406	83300	0001323131-3	propyleneglycol monostearate	yes	no	no			
407	87040	0001330561-4	sodium tetraborate	yes	no	no		(16)	
408	82960	0001330181-9	propyleneglycol monooleate	yes	no	no			
409	62240	0001332151-2	zinc oxide	yes	no	no			
1 ^{F10} 410	62720	0001332581-7	zinc	yes	no	no			Particles can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w

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

									in an ethylene vinyl alcohol 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 100 – 1 200 nm which may form agglomerates within the size

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

									2,5 % w/w.
412	45200	0001335	520-5 potassium iodide	yes	no	no		(6)	
413	35600	0001336	216-0 ammonium hydroxide	yes	no	no			
414	87600	0001338	366-1 sorbitan monolaurate	yes	no	no			
415	87840	0001338	416-1 sorbitan monostearate	yes	no	no			
416	87680	0001338	468-1 sorbitan monooleate	yes	no	no			
417	85680	0001343	182-2 sulfuric acid	yes	no	no			
418	34720	0001344	288-1 aluminum oxide	yes	no	no			
419	92150	0001401	55-4 fatty acids	yes	no	no			According to the JECFA specifications
420	19210	0001459	903-4 phthalic acid, dimethyl ester	no	yes	no	0,05		
[^{F14} 421	13000	0001477	155-0 benzene dimethanamine	no	yes	no		(34)]	
422	38515	0001533	445-5 bis(2- benzoxazolyl)stilbene	yes	no	yes	0,05		(2)
423	22937	0001623	058-0 propyl ether	no	yes	no	0,05		
424	15070	0001647	116-1 decadiene	no	yes	no	0,05		
425	10840	0001663	307-4 acetic acid, tert- butyl ester	no	yes	no		(22)	
426	13510	0001675	522-3 bis(4- hydroxyphenyl)propane	no	yes	no			In compliance with Commission Regulation (EC)
	13610		523-3 bis(2,3- epoxypropyl) ether						

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

									No 1895/2005 ^a
427	18896	0001679451-2	(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05		
428	95200	0001709170-52	tris(2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no			
429	13210	0001761574-4	aminocyclohexylmethane	no	yes	no	0,05		
430	95600	0001843103-34	tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	yes	no	yes	5		
431	61600	0001843205-6	hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)	
432	12280	0002035475-8	anhydride	no	yes	no			
433	68320	0002082070-3	decyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6		
434	20410	0002082817-1	acrylic acid, diester with 1,4-butanediol	yes	yes	no	0,05		
435	14230	0002123241-1	lactam, sodium salt	yes	yes	no		(4)	
436	19480	0002146171-6	acid, vinyl ester	no	yes	no			
437	11245	0002156071-1	ic acid,	no	yes	no	0,05		(2)

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

			dodecyl ester						
[F13]	438	13303	0002162574(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 I
	439	21280	00021777010 methacrylic acid, phenyl ester	no	yes	no		(23)	
	440	21340	00022102818 methacrylic acid, propyl ester	no	yes	no		(23)	
	441	38160	00023156686 sebacic acid, propyl ester	no	yes	no			
	442	13780	0002425179-8 butanediol bis(2,3-epoxypropyl)ether	no	yes	no	ND		Residual content = 1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.
	443	12788	0002432199-7 aminoundecanoic acid	no	yes	no	5		
	444	61440	00024402204 2,2-dihydroxy-5'-methylphenyl)benzotriazole	yes	no	no		(12)	
	445	83440	00024660903 pyrophosphoric acid	no	no	no			

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

446	10750	0002495	35-46 acrylic acid, benzyl ester	no	yes	no		(22)		
447	20080	0002495	35-46 acrylic acid, benzyl ester	no	yes	no		(23)		
448	11890	0002499	50-46 acrylic acid, n-octyl ester	no	yes	no		(22)		
[^{F11} 449	49840	0002500	48-46 dibutyl disulphide	no	yes	no	0,05]			
450	24430	0002561	88-88 basic anhydride	no	yes	no				
451	66755	0002682	220-4 methyl-4-isothiazolin-3-one	yes	no	no	0,5			Only to be used in aqueous polymer dispersions and emulsions
[^{F13} 452	38885	0002725	224-6 bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	5]			
453	26320	0002768	02-7 trimethoxyisane	no	yes	no	0,05			(10)
454	12670	0002855	113-2 amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6			
455	20530	0002867	47-42 methacrylic acid, 2-(dimethylamino)-ethyl ester	no	yes	no	ND			
456	10810	0002998	08-46 acrylic acid, sec-	no	yes	no		(22)		

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

			butyl ester							
457	20140	0002998	818-17-1 methacrylic acid, sec-butyl ester	yes	no		(23)			
458	36960	0003061	75-4 benzamide	no	no					
459	46870	0003135	318-01-1 tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no					
460	14950	0003173	531-3 hexyl isocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)	
461	22420	0003173	3472-6 naphthalene diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)	
462	26170	0003195	578-6 vinyl-N-methylacetamide	no	yes	no	0,02		[F ⁹ (1)]	
463	25840	0003290	192-4 trimethylolpropane trimethacrylate	no	yes	no	0,05			
464	61280	0003293	3297-8 hydroxy-4-n-hexyloxybenzophenone	yes	no	yes	(8)			
465	68040	0003333	3762-8 naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no				

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

466	50640	0003648	818-8 dioctyltin dilaurate	yes	no	no		(10)		
467	14800	3724-6540 45600]	40 protonic acid	yes	yes	no		(35)		
	45600]									
468	71960	0003825	26 fluorocetanoic acid, ammonium salt	no	no	no			Only to be used in repeated use articles, sintered at high temperatures	
469	60480	0003864	2921 hydroxy-3,5'- di-tert- butylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896	2125 hydroxy-3'- tert- butyl-5'- methylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
471	24888	0003965	555-7 sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066	207-8 methylenebis(4- methyl-6- cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074	4012 acid, divinyl ester	no	yes	no	ND		5 mg/ kg in final product. Only to be used as co- monomer.	(1)
474	43600	0004080	1333 chloroallyl)-3,5,7-	yes	no	no	0,3			

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

			triazolone adamantane chloride							
475	19110	0004098	171-9 isocyanato-3- isocyanatomethyl-3,5,5- trimethylcyclohexane	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
476	16570	0004128	171-8 diphenyl ether-4,4'- diisocyanate	yes	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
477	46720	0004130	246- di-tert- butyl-4- ethylphenol	yes	no	yes	4,8			(1)
478	60180	0004191	1473-5 hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	0004196	251-6 phthalic anhydride	no	yes	no				
480	46790	0004221	380- di-tert- butyl-4- hydroxybenzoic acid, 2,4-di- tert- butylphenyl ester	yes	no	no				
481	13060	0004422	195-5 benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5- benzenetricarboxylic acid	[F9(1)]
482	21100	0004655	3419- methacrylic acid,	yes	yes	no		(23)		

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

			isopropyl ester							
483	68860	0004724	448-5 octylphosphonic acid	yes	no	no	0,05			
484	13395	0004767	202-7 bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)
485	13560 15700	0005124	301-1 hexamethylene diisocyanate	yes	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
486	54005	0005136	441-7 N-palmitamide-N'-stearamide	yes	no	no				
487	45640	0005232	299-5 cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05			
488	53440	0005518	181-3 ethylenebispalmitamide	yes	no	no				
489	41040	0005743	361-2 calcium butyrate	yes	no	no				
490	16600	0005873	511-1 4,4'-diphenylmethane diisocyanate	yes	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	0006182	112-2 propyleneglycol distearate	yes	no	no				
492	45650	0006197	230-4 cyano-3,3-diphenylacrylic acid, 2-	yes	no	no	0,05			

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

			ethylhexyl ester							
493	39200	0006200	641-2 hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	yes	no	no	1,8			
494	62140	0006303	37-5 phosphoric acid	no	no					
495	35160	0006642	631-5 amino-1,3-dimethyluracil	yes	no	no	5			
496	71680	0006683	91-8 tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	no	no					
497	95020	0006846	25-4 trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5			Only to be used in single-use gloves
498	16210	0006864	33-5 dimethyl-4,4'-diaminodicyclohexylmethane	no	yes	no	0,05			Only to be used in polyamides (5)
499	19965 65020	0006915	11-7 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

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

									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				
502	22778	0007456468-0	oxybis(benzenesulphonyl azide)	no	yes	no	0,05			[F ⁹ (1)]
503	46080	0007585839-9	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	0007631860-0	bisulphite	yes	no	no		(19)		

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

506	86920	000763250010	Iron nitrite	yes	no	no	0,6			
507	59990	000764710110	Hydrochloric acid	yes	no	no				
508	86560	000764750160	Sodium bromide	yes	no	no				
509	23170	000766418200	Phosphoric acid	yes	yes	no				
	72640									
510	12789	000766441170	Ammonia	yes	yes	no				
	35320									
511	91920	000766450190	Phosphoric acid	yes	no	no				
512	81680	000768110160	Potassium iodide	yes	no	no		(6)		
513	86800	000768150160	Sodium iodide	yes	no	no		(6)		
514	91840	000770451190	Sulphur	yes	no	no				
515	26360	000773210150	Water	yes	yes	no				In compliance with Directive 98/83/EC ^b
	95855									
516	86960	000775780170	Sodium sulphite	yes	no	no		(19)		
517	81520	000775800130	Potassium bromide	yes	no	no				
518	35845	000777140160	Maleic acid	yes	no	no				
519	87120	000777250170	Sodium thiosulphate	yes	no	no		(19)		
520	65120	000777330150	Manganese chloride	yes	no	no				
521	58320	000778250150	Zinc white	yes	no	no				
522	14530	000778250150	Zinc white	no	yes	no				
523	45195	000778700160	Copper bromide	yes	no	no				
524	24520	000800150170	Castor oil	no	yes	no				
525	62640	000800150160	Japan wax	yes	no	no				

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

526	43440	0008001	le7560 le7560	yes	no	no				
527	14411	0008001	le794 le794	yes	yes	no				
	42880		oil							
528	63760	0008002	le435 le435	yes	no	no				
529	67850	0008002	le507 le507	yes	no	no				
530	41760	0008006	le448 le448	yes	no	no				
531	36880	0008012	le893 le893	yes	no	no				
532	88640	0008013	le078 le078	yes	no	no	60 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined

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

541	58480	000900060115	gum arabic	yes	no	no				
542	42640	000900061170	cellulose methylcellulose	yes	no	no				
543	45920	000900061620	cellulose	yes	no	no				
544	58400	000900063100	gum	yes	no	no				
545	93680	000900065100	gum	yes	no	no				
546	71440	000900066010	polypropylene	yes	no	no				
547	55440	000900067010	polypropylene	yes	no	no				
548	42800	000900067110	polypropylene	yes	no	no				
549	80000	000900268400	polyethylene wax	yes	no	no				
550	81060	000900360700	polypropylene wax	yes	no	no				
551	79920	00090036106392	poly(ethylene glycol)	yes	no	no				
552	81500	000900360980	polyvinylpyrrolidone	yes	no	no				The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC ^c
553	14500	000900463110	cellulose	yes	yes	no				
	43280									
554	43300	000900463110	cellulose acetate butyrate	yes	no	no				
555	53280	000900465700	cellulose	yes	no	no				
556	54260	000900465810	cellulose hydroxyethylcellulose	yes	no	no				
557	66640	000900465915	cellulose hydroxyethylcellulose	yes	no	no				
558	60560	000900466200	cellulose hydroxyethylcellulose	yes	no	no				
559	61680	000900466420	cellulose hydroxypropylcellulose	yes	no	no				

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

560	66700	00090046513	hydroxypropylcellulose	yes	no	no			
561	66240	00090046515	cellulose	no	no	no			
562	22450	00090047000	cellulose	yes	no	no			
563	78320	00090049071	polyethylene glycol monoricinoleate	yes	no	yes	42		
564	24540	00090052528	starch, edible	yes	yes	no			
	88800								
565	61120	00090052710	hydroxyethyl starch	yes	no	no			
566	33350	00090052917	alginate acid	yes	no	no			
567	82080	00090054372	propyleneglycol alginate	yes	no	no			
568	79040	00090056456	polyethylene glycol sorbitan monolaurate	yes	no	no			
569	79120	00090056566	polyethylene glycol sorbitan monooleate	yes	no	no			
570	79200	00090056677	polyethylene glycol sorbitan monopalmitate	yes	no	no			
571	79280	00090056788	polyethylene glycol sorbitan monostearate	yes	no	no			
572	79360	00090057093	polyethylene glycol sorbitan trioleate	yes	no	no			
573	79440	00090057144	polyethylene glycol sorbitan tristearate	yes	no	no			
574	24250	00090060466	orbiter, natural	yes	yes	no			
	84560								
575	76721	00631486299	dimethylsiloxane (Mw > 6 800 Da)	yes	no	no			Viscosity at 25 °C not less than 100 cSt (100 ×

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

									10 ⁻⁶ m ² /s)
576	60880	00090324	hydroxyethylmethylcellulose	yes	no	no			
577	62280	00090441	isobutylene-butene copolymer	yes	no	no			
578	79600	00090460	polyethyleneglycol tridecyl ether phosphate	yes	no	no	5		For materials and articles intended for 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	00090491	hydroxypropyl starch	yes	no	no			
580	46070	00100162	20-3 dextrin	yes	no	no			
581	36800	00100221	barium nitrate	yes	no	no			
582	50240	00100391	3-5 octyltin bis(2-ethylhexyl maleate)	yes	no	no		(10)	

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

583	40400	00100435	boron nitride	yes	no	no		(16)		
584	13620	00100435	boric acid	yes	yes	no		(16)		
	40320									
585	41120	00100435	lead(II) chloride	yes	no	no				
586	65280	00100435	manganese hypophosphite	yes	no	no				
587	68400	00100944	secbutylsuccinimide	yes	yes	yes	5			
588	64320	00103771	lithium iodide	yes	no	no		(6)		
589	52645	00104360	18-eicosenamide	yes	no	no				
590	21370	00105958	acrylic acid, 2-sulphoethyl ester	yes	no	no	ND			(1)
591	36160	00106058	ethyl stearate	yes	no	no				
592	34690	00110975	magnesium carbonate hydroxide	yes	no	no				
593	44960	00111046	cobalt oxide	yes	no	no				
594	65360	00111296	manganese oxide	yes	no	no				
595	19510	00111321	cellulose	yes	no	no				
596	95935	00111386	chondroitin sulphate	yes	no	no				
597	67120	00120012	nickel	yes	no	no				
598	41600	00120044	lead(II) phosphate	yes	no	no				
599	36840	00120075	tetraborate	yes	no	no		(16)		
600	60030	00120725	brucite	yes	no	no				
601	35440	00121248	potassium bromide	yes	no	no				
602	70240	00121989	kerite	yes	no	no				
603	83460	00122697	phenylacetylene	yes	no	no				

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

604	60080	001230465-3	Hydrolytic	no	no				
605	11005	001254230-2	2,3-Di- acid, dicyclopentenyl ester	no	yes	no	0,05		(1)
606	65200	001262688-9	Organic hydroxide	no	no				
607	62245	001275120-3	Iron-3 phosphide	yes	no	no			Only to be used in PET polymers and copolymers
608	40800	001300341-8	butylidene- bis(6- tert- butyl-3- methylphenyl- ditridecyl phosphite)	yes	no	yes	6		
609	83455	001344556-2	Phosphorous acid	no	no	no			
610	93440	001346367-7	Tungsten dioxide	yes	no	no			
611	35120	001356034-1	aminocrotonic acid, diester with thiobis (2- hydroxyethyl) ether	yes	no	no			
612	16694	001381150-2	2,2- divinyl-2- imidazolidinone	no	yes	no	0,05		(10)
613	95905	001398370-1	Hydrolytic	no	no				
614	45560	001446465-1	Hydrolytic	no	no				
615	92080	001480716-6	Hydrolytic	yes	no	no			
616	83470	001480860-7	Carbon	yes	no	no			
617	10660	001521428-8	acrylamido-2-	no	yes	no	0,05		

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

			methylpropanesulphonic acid						
618	51040	0015535	479-2 octyltin mercaptoacetate	yes	no	no		(10)	
619	50320	0015571	458-1 octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)	
620	50720	0015571	460-5 octyltin dimaleate	yes	no	no		(10)	
621	17110	0016219	575-3 ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05		(9)
622	69840	0016260	009-6 palmitylamide	no	no	yes	5		
623	52640	0016389	488-1 zinc stearate	yes	no	no			
624	18897	0016712	264-4 hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05		
625	36720	0017194	400-2 zinc hydroxide	yes	no	no			
626	57800	0018641	574-1 glycerol tribehenate	yes	no	no			
627	59760	0019569	421-2 zinc stearate	yes	no	no			
628	96190	0020427	581-1 zinc hydroxide	yes	no	no			
629	34560	0021645	511-1 zinc hydroxide	yes	no	no			
630	82240	0022788	12-8 propyleneglycol dilaurate	yes	no	no			
631	59120	0023128	476-7 hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45		
632	52880	0023676	409-7 ethoxybenzoic acid,	yes	no	no	3,6		

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

			ethyl ester						
633	53200	00239492	66-8 ethoxy-2'-ethyloxanilide	yes	no	yes	30		
634	25910	00248004	14-0 propylene glycols			no			
635	40720	00250134	16-5 butyl-4-hydroxyanisole	yes	no	no	30		
636	31500	00251345	14-1 acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester
637	71635	00251519	26-6 pentaerythritol dioleate		no	no	0,05		Not to be used for articles in contact with fatty foods for which [F2 simulant D1 and/or D2] is laid down
638	23590	00253222	68-3 polybutylene glycols	yes		no			
	76960								
639	23651	00253222	69-4 polypropylene glycol			no			
	80800								
640	54930	00253599	91-1 formaldehyde-naphthol, copolymer		no	no	0,05		
[F2 641	22331	00255133	64-8 of (35-45 % w/w) 1,6-	no	yes	no	0,05]		

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

			diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane						
642	64990	0025736	maleic anhydride-styrene, copolymer, sodium salt	yes	no	no			The fraction with molecular weight below 1 000 Da [F ₂ shall] not exceed 0,05 % (w/w)
643	87760	0026266	7799 monopalmitate	yes	no	no			
644	88080	0026266	5800 trioleate	yes	no	no			
645	67760	0026401	8615 n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no	(11)		
646	50480	0026401	4978 octyltin bis(isooctyl mercaptoacetate)	yes	no	no	(10)		
647	56720	0026402	2363 glycerol mono-hexanoate	yes	no	no			
648	56880	0026402	2366 glycerol mono-octanoate	yes	no	no			
649	47210	0026427	4076 ethylthio stannonic acid polymer	no	no	no			Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)
650	49600	0026636	0111 methyltin bis(isooctyl mercaptoacetate)	yes	no	no	(9)		

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

651	88240	0026658	150-7	sofitan tristearate	yes	no	no			
652	38820	0026741	153-74	di-tert-butylphenyl pentaerythritol diphosphite	yes	no	yes	0,6		
653	25270	0026747	290-0	toluene diisocyanate dimer	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
654	88600	0026836	47-7	monostearate	yes	no	no			
655	25450	0026896	48-0	decanedimethanol	no	no	no	0,05		
656	24760	0026914	43-2	styrenesulphonic acid	yes	yes	no	0,05		
657	67680	0027107	78-7	n-octyltin tris(2-ethylhexyl mercaptoacetate)	yes	no	no		(11)	
658	52000	0027176	87-0	decylbenzenesulphonic acid	no	no	no	30		
659	82800	0027194	72-7	propyleneglycol monolaurate	yes	no	no			
660	47540	0027458	90-8	tert-dodecyl disulphide	yes	no	yes	0,05		
661	95360	0027676	62-5	tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	5		
662	25927	0027955	94-8	tris(4-hydroxyphenyl)ethane	no	yes	no	0,005		Only to be used in polycarbonates [F9(1)]

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

663	64150	002829017011	1,7-dihydroxycyclohexanecarboxylic acid	yes	no	no			
664	95000	0028931671	1,6-hexamethylene trimethacrylate-methyl methacrylate copolymer	no	no	no			
665	83120	0029013128	3-propyleneglycol monopalmitate	yes	no	no			
666	87280	0029116508	1,6-hexanediol diolate	yes	no	no			
667	55190	0029204902	1,3-bis(2-hydroxyethyl)glycerol sebacate	yes	no	no			
668	80240	0029894357	1,3-bis(2-hydroxyethyl)glycerol ricinoleate	yes	no	no			
669	56610	0030233658	1,3-bis(2-hydroxyethyl)glycerol monobehenate	yes	no	no			
670	56800	0030899658	1,3-bis(2-hydroxyethyl)glycerol monolaurate diacetate	yes	no	no	(32)		
671	74240	0031570045	1,4-bis(2-hydroxyethyl)phosphoric acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no			
672	76845	0031831515	1,5-hexanediol of 1,4-butanediol with caprolactone	yes	no	no	(29) (30)	The fraction with molecular weight below 1 000 Da [F ² shall] not exceed 0,5 % (w/w)	
673	53670	0032509661	1,6-hexanediol glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6		

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

674	46480	0032647	467-9 bis(2-azylidene sorbitol)	no	no			
675	38800	0032687	778-8 bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15	
676	50400	0033568	499-9 octyltin bis(isooctyl maleate)	yes	no	no		(10)
677	82560	0033587	420-1 propyleneglycol dipalmitate	yes	no	no		
678	59200	0035074	476-2 hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	yes	no	yes	6	
679	39060	0035958	430-6 bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5	
680	94400	0036443	681-2 bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	yes	no	no	9	
681	18310	0036653	482-4 hexadecanol	no	yes	no		
682	53270	0037205	605-5 ethylcarboxymethylcellulose	yes	no	no		
683	66200	0037206	604-2 methylcarboxymethylcellulose	yes	no	no		
684	68125	0037244	606-1 ephaline syenite	yes	no	no		
685	85950	0037296	476-2 acid, magnesium-sodium-fluoride salt	yes	no	no	0,15	SML expressed as fluoride. Only to be used

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

										in layers of multi-layer materials not coming into direct contact with food.
686	61390	0037353	5906	hydroxyethylcellulose	no					
687	13530	0038103	205-9	bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05		
	13614									
688	92560	0038613	7713	di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	yes	no	yes	18		
689	95280	0040601	176,51	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	0041484	465-9	bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	no	yes	yes	2,4		
691	13600	0047465	397-4	bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8		
692	52320	0052047	25043	dodecylphenylindole	yes	no	yes	0,06		

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

693	88160	005414030614	sofbitan yes tripalmitate	no	no				
694	21400	00542763516	acrylic acid, sulphopropyl ester	yes	no	0,05			(1)
695	67520	0054849386	trimethyltin tris(isooctyl mercaptoacetate)	no	no		(9)		
696	92205	0057569401	phthalic acid, diester with 2,2'- methylenebis(4- methyl-6- tert- butylphenol)	no	no				
697	67515	0057583343	trimethyltin tris(ethylhexyl mercaptoacetate)	no	no		(9)		
698	49595	0057583354	dimethyltin bis(ethylhexyl mercaptoacetate)	no	no		(9)		
699	90720	0058446529	styrene, benzoyl methane	no	no				
700	31520	0061167587	phthalic acid, 2-tert- butyl-6- (3-tert- butyl-2- hydroxy-5- methylbenzyl)-4- methylphenyl ester	yes	no	yes	6		
701	40160	0061269612	N,N2 bis(2,2,6,6- tetramethyl-4- piperidyl)hexamethylenediamine-1,2- dibromoethane, copolymer	yes	no	no	2,4		
702	87920	0061752689	sofbitan yes tetrastearate	no	no				
703	17170	0061788674	fatty acids, coco	no	yes	no			

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

704	77600	0061788	85-014 polyethylene glycol ester of hydrogenated castor oil	yes	no	no			
705	10599/90 10599/91	0061788	88-014 fatty, unsaturated (C ₁₈), dimers, non hydrogenated, distilled and non-distilled	no	yes	no		(18)	(1)
706	17230	0061790	12-03 fatty acids, tall oil	no	yes	no			
707	46375	0061790	53-02 china clay earth	no	no	no			
708	77520	0061791	12-01 polyethylene glycol ester of castor oil	yes	no	no	42		
709	87520	0062568	11-01 sorbitan monobehenate	yes	no	no			
710	38700	0063397	66-02 bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	yes	no	yes	18		
711	42000	0063438	80-02 tris(2-carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	yes	no	yes	30		
712	42960	0064147	46-06 castor oil, dehydrated	yes	no	no			
[^{F10} 713	43480	0064365 0007440-44-0]	34-03 charcoal activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer.

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

									Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Regulation (EU) No 231/2012 ^d with exception of ash content which can be up to 10 % (w/w).
714	84400	006436510719	hydrogenated, ester with pentaerythritol	yes	no	no			
715	46880	006514039101	tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6		
716	60800	00654471720	(4-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30		
717	84210	006599710611	hydrogenated	yes	no	no			

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

718	84240	0065997	43-9 hydrogenated, ester with glycerol	yes	no	no			
719	65920	0066822	60-4 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	65-4 n- dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no	(25)		
721	46800	0067845	35-6 tert- butyl-4- hydroxybenzoic acid, hexadecyl ester	yes	no	no			
722	17200	0068308	50-2 acids, soya	no	yes	no			
723	88880	0068412	20-1 starch, hydrolysed	yes	no	no			
724	24903	0068425	7-2 starch, hydrolysed starch, hydrogenated	no	yes	no			In compliance with the purity criteria for maltitol

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

									syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ^e	
F16										
726	83599	0068442	2-2-6 reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes		(9)		
727	43360	0068442	2-8-10 Fluorescein regenerated	yes	no	no				
728	75100	0068515 0028553	4-10 3-10 Aliphatic diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than 60 % C ₉	yes	no	no		(26) (32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except

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

									for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
729	75105	0068515 0026761	Phthalic diesters with primary, saturated C ₉ -C ₁₁ alcohols	yes	no	no	(26) (32)	Only to be used as: (a)	(7) plasticiser in repeated use

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

		more than 90 % C ₁₀						(b)	materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;
								(c)	technical support agent in concentrations up

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

										to 0,1 % in the final product.
730	66930	0068554	47011	no	yes	no				Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane
731	18220	0068564	488-5	no	yes	no	0,05			(2)
732	45450	0068610	051-5	yes	no	yes	5			
733	10599/92 10599/93	0068783	4115	no	yes	no		(18)		(1)
734	46380	0068855	5410	no	no	no				
735	40120	0068951	5018	yes	no	no				
736	50960	0069226	644-4	yes	no	no		(10)		
737	77370	0070142	2046	yes	no	no				
738	60320	0070321	285-7	yes	no	yes	1,5			

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

			bis(1,1-dimethylbenzyl)phenyl]benzotriazole						
739	70000	0070331292	1-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no			
740	81200	00718786098	[(1,1,3,3-tetramethylbutylamino)-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl imino]	yes	no	yes	3		
741	24070	0073138836	acids and rosin acids	yes	yes	no			
	83610								
742	92700	007830124	2,4-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			
[^{F15} 744	18888	080181-31	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no		(35)	The substance is used as product obtained by bacterial fermentation. In compliance with

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

									the specifications mentioned in the Table 4 of Annex I.]
745	68145	0080410233	2,2',3,3'-nitriolo(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	0080693600	2,6-di-tert-butyl-4-methylphenyl)diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
747	47600	0084030615	1,5-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)	
748	12765	0084434128	2-(2-aminoethyl)- β -alanine, sodium salt	no	yes	no	0,05		
749	66360	0085209221	2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5		
750	66350	0085209224	2,2'-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5		
751	81515	0087189251	2,5-bis(zinc glycerolate)	yes	no	no			

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

F ²	752	39890	008782644-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(methylene)diphenylsulfone	yes	no	no			
	753	62800	009270440-1 calcined	kaolin	yes	no	no			
	754	56020	009988064-6 dibhenate	glycerol	yes	no	no			
	755	21765	010624643-7	methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05		(1)
	756	40020	011055322-0	bis(octylthiomethyl)-6-methylphenol	yes	no	yes		(24)	
	757	95725	011063871-6 reaction product with citric acid, lithium salt	fluorolite	yes	no	no			
	758	38940	011067522-8	bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes		(24)	
	759	54300	011833720-0	ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6		
	760	83595	011934510-0 reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft	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 (*)),

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

		reaction product of phosphorous trichloride and biphenyl					—	4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)),
							—	3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)),
							—	4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),
							—	tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)),

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

									—	4,4'-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*)
									(*)	Quantity of substance used/ quantity of formulation
									Other specifications:	
									—	Phosphor content of min. 5,4 % to max. 5,9 %,
									—	Acid value of max. 10 mg KOH per gram,
									—	Melt range of 85–110 °C,
761	92930	0120218	Bis(2-ethoxycarbonyl-1,4-	no	no	6				

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

			dihydropyridine-3-carboxylate)							
762	31530	0123968	25-1c acid, 2,4-di- tert- pentyl-6- (1- (3,5- di-tert- pentyl-2- hydroxyphenyl)ethyl)phenyl ester	yes	no	yes	5			
763	39925	0129228	32-3 bis(methoxymethyl)-2,5- dimethylhexane	yes	no	yes	0,05			
764	13317	0132459	54-2 bis[4- (ethoxycarbonyl)phenyl]-1,4,5,8- naphthalenetetracarboxydiimide	no	yes	no	0,05		Purity > 98,1 % (w/w). Only to be used as co- monomer (max 4 %) for polyesters (PET, PBT).	
765	49485	0134701	20-5 dimethyl-6- (1- methylpentadecyl)phenol	yes	no	yes	1			
766	38879	0135861	54-2 bis(2,4- dimethylbenzylidene)sorbitol	yes	no	no				
767	38510	0136504	25-6 bis(3- aminopropyl)ethylenediamine, polymer with N- butyl-2,2,6,6- tetramethyl-4- piperidinamine and 2,4,6-	yes	no	no	5			

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

			trichloro-1,3,5-triazine						
768	34850	0143925	Articles, yes bis(hydrogenated tallow alkyl) oxidised	no	no			Not to be used for articles in contact with fatty foods for which [F ² 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. (b)	(1)
769	74010	0145650	phosphoric acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	yes	no	yes	5	SML expressed as sum of phosphite and phosphate	
770	51700	0147315	2,4-bis(diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05		

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

771	34650	0151841	65-11-11-yes hydroxybis [2,2'- methylenebis (4,6- di-tert- butylphenyl) phosphate]	no	no	5			
772	47500	0153250	52-13-yes dicyclohexyl-2,6- naphthalene dicarboxamide	no	no	5			
773	38840	0154862	43-24-yes dicumyl(phenyl)pentaerythritol- diphosphite	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	0161717	24-64-yes tris(tert- butylphenyl)-2- butyl-2- ethyl-1,3- propanediol phosphite	no	yes	2			SML expressed as sum of phosphite, phosphate and the hydrolysis product = TTBP
775	45705	0166412	17-8-yes cyclohexanedicarboxylic acid, diisononyl ester	no	no		(32)		
776	76723	0167883	16-11-yes polydimethylsiloxane, 3- aminopropyl terminated,	no	no				The fraction with molecular

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

			polymer with dicyclohexylmethane-4,4'-diisocyanate					weight below 1 000 Da [F ² shall] not exceed 1,5 % (w/w)	
777	31542	0174254	23-allylic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters	yes	no	no		0,5 % in final product	(1)
778	71670	0178671	584-erythritol tetrakis (2-cyano-3,3-diphenylacrylate)	no	yes	0,05			
[F ² 779]	39815	0182121	192-6 bis(methoxymethyl)fluorene	yes	no	yes	0,05		[F ⁹ (2)]
780	81220	0192268	647 [[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino]-1,3,5-triazine-2,4-diyl] [(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-	yes	no	no	5		

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

			tetramethyl-4-piperidinyl)-N"-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]						
781	95265	02270994	0,5-tris(4-benzoylphenyl)benzene	yes	no	no	0,05		
782	76725	0661476	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 ² shall] not exceed 1 % (w/w)
783	55910	0736150	glycerides, castor-oil mono-, hydrogenated, acetates		no	no		(32)	
[F ¹⁰ 784	95420	0745070	1,5-tris(2,2-dimethylpropanamido)benzene	yes	no	no	5]		
785	24910	0000100	terephthalic acid	yes	no			(28)	

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

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- tetradecene (Mw: 440– 12 000)	yes	no	no			Average (2) molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10 ⁻⁶ m ² /s).	
790	80480	0090751 0082451	140786- 1487 triazine-2,4- diyl)- [(2,2,6,6- tetramethyl-4- piperidyl)imino]]	yes	no	no	5		Average (16) molecular weight not less than	

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

			hexa- methylene- [(2,2,6,6- tetramethyl-4- piperidyl)imino]						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- bis(N- butyl- (N- methyl-2,2,6,6- tetramethylpiperidin-4- yl)amino)triazin-2- yl)-4,7- diazadecane-1,10- diamine	yes	no	no	0,05		
792	92475	0203255	3,3',5,5'- tetrakis(tert- butyl)-2,2'- dihydroxybiphenyl, cyclic ester with [3-(3- tert- butyl-4- hydroxy-5- methylphenyl)propyl]oxyphosphonous acid	yes	no	yes	5		SML expressed as the sum of phosphite and phosphate form of the substance and the

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

									hydrolysis products
793	94000	0000102	triethanolamine	no	no	0,05			SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine
[^{F13} 794	18117	0000079	glycolic acid	no	yes	no			Only to be used 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

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

									or PLA.]	
795	40155	0124172	N,N-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine	yes	no	no	0,05			(2) (12)
796	72141	0018602	(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	yes	no	yes	0,05		SML including the sum of its hydrolysis products	
[^{F13} 797	76807	0073018	2,6-hexylenedioxyadipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)]		
798	92200	0006422	terephthalic acid, bis(2-ethylhexyl)ester	yes	no	no	60	(32)		
[^{F10} 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 for food additives in Commission Regulation	

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

									(EU) No 231/2012. I	
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 maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	yes	no	no			Not to be used for articles in contact with fatty foods for which [F ₂ simulant D1 and/or D2] is laid down. Not to be used in contact	(13)

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

									with alcoholic foods.
804	80510	1010121	poly(3-nonyl-1,1-dioxo-1-thiopropyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	yes	no	no			Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)
805	93450	—	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	yes	no	no			The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w
806	14876	0001076	cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters
[F11]807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles.

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

									Only to be used in polyethylene terephthalate (PET) up to 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. I
808	38550	0882073	14-4 bis(4-propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products
809	49080	0852282	14-4 (2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3-dione	yes	no	yes	0,05		Only for use in PET (6) (14) (15)
810	68119		neopentyl glycol, diesters and	yes	no	no	5	(32)	Not to be used for

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

			monoesters with benzoic acid and 2-ethylhexanoic acid					articles in contact with fatty foods for which [F ² simulant D1 and/or D2] is laid down.
811	80077	006844	polyethylene waxes, oxidised	no	no	60		
[F ¹³ 812	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.
813	91530	—	sulphosuccinic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts	no	no	5		
814	91815	—	sulphosuccinic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol	no	no	2		

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

			esters, salts						
815	94985	—	trimethylpropyl mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid	yes	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which [F ² simulant D1 and/or D2] is laid down
816	45704	—	cis-1,2-cyclohexanedicarboxylic acid, salts	yes	no	no	5		
817	38507	—	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	yes	no	no	5		Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %.
818	21530	—	methallylsulphonic acid, salts	yes	no	no	5		
819	68110	—	neodecanoic acid, salts	yes	no	no	0,05		Not to be used in polymers contacting fatty foods. Not to be

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

									used for articles in contact with fatty foods for which [F ² 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				
[F ¹⁷ 822	71938		Perchloric acid, salts	yes	no	no	0,002			(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 and perfluoro-1,1-ethylene	yes	no	no			Only to be used in concentrations up to 0,5 % w/w in the polymerisation of fluoropolymers that are processed	

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

			glycol, terminated with chlorohexafluoropropoxy groups					at temperatures at or above 340 °C and are intended for use in repeated use articles	
[^{F18} 855	40560		(butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.	
[^{F19} 856	40563	25101-28	(butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate	no	no			Only to be used in: — rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below; or	

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

												at up to 40 % w/ w in blends of styrene acrylonitrile copolymer (SAN)/ poly(methyl methacrylate) (PMMA) repeat- use articles at room temperature or below, and when either in contact only with aqueous, acidic and/ or low alcoholic (< 20 %) foodstuffs for less than 1 day, or when in contact only with dry foodstuffs for any duration of
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I. (See end of Document for details)

										time. I
857	66765	0037953	(2) methyl 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. I
[F7][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-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

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

								methid tautomer.
[F ⁴ 859			(butadiene, 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 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

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

								sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm. I
860	71980	0051798	perfluoropoly- (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	perfluoropoly- (n-propoxy)propanoic acid]	no	no			Only to be used in the polymerisation of fluoropolymers that are

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

									processed at temperatures at or above 265 °C and are intended for use in repeated use articles
[^{F13} 862	15180	0018085302-4	no diacetoxy-1-butene	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.
[^{F18} 863	15260	000064642503	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

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

										and dairy foodstuffs at room temperature or for short term contact up to 150 °C. I
864	46330	0000056206-4	206-4 diamino-6-hydroxypyrimidine	yes	no	no	5			Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic aqueous food
[F11] 865	40619	0025322(00-01	00-01 acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no				Only to be used in: (a) rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w; (b) polylactic acid (PLA) at a

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

										maximum level of 5 % w/w.
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 %	
[^{FI} 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 % w/w; (b) polylactic acid (PLA) at	

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

											a maximum level of 5 % w/w; polyethylene terephthalate (PET) at a maximum level of 5 % w/w.
869	66763	002713641518	66763 (acrylate, methyl methacrylate, styrene) copolymer	yes	no	no				Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 %	
870	95500	01605351406	95500 N,N'-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide	yes	no	no	5				
[^{F20} 871		0287916843	871 6843 acetic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-	yes	no	no				Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall	(23)]

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

			ethanediy) and 1-propene					only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food.	
[^{F21} 872		0006607	241-6 phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	no	yes	no	0,05	To be used only as a co-monomer in polycarbonate copolymers	(20)]
[^{F18} 873	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no		Reaction product of titanium dioxide	

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

									with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures.]
[F7874	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	005812821-612	poly(12-hydroxystearic acid) stearate	yes	no	yes	5		
878	31335	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats	yes	no	no			

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

			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			
[^{F10} 880	31348		acids, fatty (C ₈ - C ₂₂), esters with pentaerythritol'	yes	no	no			
881	25187	000301029644-	tetramethylcyclobutane-1,3-diol	no	yes	no	5	Only for: (a)	repeated use articles for long term storage at room

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

										of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles. I
882	25872	0002416293,6	293,6 trimethylphenol	no	yes	no	0,05			
883	22074	0004457371-0	371-0 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	

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

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 [F ² 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 concentrations up to 1 % w/w, in contact with aqueous, acidic and alcoholic foods, for long

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

									term storage at room temperature.
[F18]	894	93360	0016545516-8	5-tert-butyl-4-hydroxyphenylpropanoic acid, ditetradecyl ester	no	no		(14)	
	895	47060	0171090393-5	3,5-di-tert-butyl-4-hydroxyphenylpropanoic 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.
	896	71958	0958445344-8	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

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

									up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles.
[^{F7} 902		000012842-9	benzothiazol-3(2H)-one 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 " .]
[^{F4} 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: (a) repeated and single use

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

923	39150	0000120404	N,N-bis(2-hydroxyethyl)dodecanamide	yes	no	no	5		The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, [F2 shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food.	(18)
924	94987		trimethylpropyl mixed triesters and diesters with n-octanoic and n-decanoic acids	no	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	0908020520	perfluoro[2-ethoxyethoxy]acetic acid], ammonium salt	no	no	no			Only to be used in the polymerisation of fluoropolymers	

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

								that are processed at temperatures higher than 300 °C for at least 10 minutes.	
[F4969		24937-78	Styleneyes vinyl acetate copolymer wax	no	no			Only to be 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	trifthaloy trimellitate	yes	no			Only to be used as a co-monomer up to 0,35 % w/w to produce modified polyesters intended to be	(17)

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

									used in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158	80746 copper hydroxide phosphate	yes	no	no			
973	22931	0019430	(93-Fluorobutyl)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.
[F17]974	74050	939402	025-phosphoric acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	10		SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration

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

									of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food. II
[^{F7} 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.]
[^{F21} 988		3634-83-1	1,3-bis(isocyanatomethyl)benzene	no	yes	no	(34)		SML(T) applies to the migration of its hydrolysis 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]

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

I ^{F4} 998			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross- linked, 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 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.
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I. (See end of Document for details)

								The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.	
[^{F22} 1007	976-56-	diethyl[1,1-bis(4-hydroxyphenyl)ethyl]phosphonate	yes	no				Only to be used up to 0,2 % w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) (PET).	
1016		(methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	no	no				Only to be used up to: (a) 10 % w/w in non-plasticised PVC; (b) 15 % w/w in non-	

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

									The final material shall be used at room temperature or below. I	plasticised PLA.
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.	
[^{F22} 1030			montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride	no	no				Only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room	

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

								temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.	
[^{F20} 1031]	3238-40-2	Iran-2,5-dicarboxylic acid	no	yes	no	5		Only to be used as a	(22) (23)

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

								monomer in the production of polyethylene furanoate. The migration of the 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-	no octadiene	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 room temperature, including when

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

								packaged under hot-fill conditions. I
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3- butanediol dimethacrylate, 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 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 998, the restriction of 10 %

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

									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. I
[^{F20} 1045	1190931	perfluoroacetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]], ammonium salt	yes	no	no				Only to be 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	yes	no	no				Only to be used in unplasticised polymers. The restrictions and specifications

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

			No 788)						specified for FCM substance No 788 shall be respected.
1048		624-03-	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 oligomers of less than 1 000 (22) (23)

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

									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]	
[^{F22} 1055	7695-91-2 58-95-7	α-tocopherol acetate	yes	no	no			Only to be used as antioxidant in polyolefins.	(24)	
[^{F23} 1059	147398-10-0	Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)	yes	no	no		(35)	Only to be used either alone or blended with other polymers in contact with all foods under contact conditions of	(23)]	

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

								up to 6 months and/or 6 months and more, at room temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5,0 mg/kg food.
1060			ground sunflower seed hulls	yes	no	no		Only to be used at room temperature or below in contact with foods for which Table 2 of Annex III assigns

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

								food simulant E. The seed hulls shall be obtained from sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240 °C.
[^{F24} 1061	80512-44-3,4'-	no	yes	no				Only to be used as a co-monomer in the manufacture of polyether ether ketone plastics up to 0,3 % w/w of the final material.
1062		mixture no composed of 97 %	yes	no				Only to be used for the

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

			tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane (HMDS) with CAS No 999-97-3				production of recycled PET and at up to 0,12 % (w/w).
[^{F24} 1063	1547-26	2,3,3,4,4,5-heptafluoro-1-pentene	yes	no			Only to be used together with tetrafluoroethylene and/or ethylene co-monomers to manufacture fluorocopolymers for application as polymer processing aid at up to 0,2 % w/w of the food contact material, and when the low-molecular mass fraction below 1 500 Da in the fluorocopolymer does not exceed

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

									30 mg/ kg.
1064		39318-18-8	styrene oxide	yes	no	no	0,05		Stoichiometry: WO n = 2,72-2,90
1065		85711-28-0	mixture of methyl-branched and linear C ₁₄ - C ₁₈ alkanamides, derived from fatty acids	yes	no	no	5		Only to be used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which food simulant D2 is assigned in Table 2 of Annex III. (26)]
[^{F15} 1066		23985-71-3	1,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester	no	yes	no	0,05		Only to be used as a co-monomer in the manufacture of a polyester non-food contact layer in a plastic multilayer

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

								material, which is to be used only in contact with foods for which food simulants A, B, C and/ or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substance and of its dimers (cyclic and open chain). I	
[^{F25} 1067	616-38-	dimethylno carbonate	yes	no				Only to be used: a)	(27)] with 1,6-hexanediol in the manufacture

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

									<p>of polycarbonate pre- polymers that are used at up to 30 % to manufacture thermoplastic polyurethanes with 4,4'- methylenediphenyldiisocya and diols, such as polypropylene glycol and 1,4- butanediol. The resulting material shall only be applied in repeated use articles intended to come into short- term contact (≤ 30 min at room temperature) with food for which</p>
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I. (See end of Document for details)

											simulants A and/ or B are assigned in Table 2 of Annex III; or for the production of other polycarbonates and/ or under other conditions provided that the migration of dimethyl carbonate does not exceed 0,05 mg/ kg food and that the migration of all polycarbonate oligomers with a molecular weight below 1 000
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I. (See end of Document for details)

									Da together does not exceed 0,05 mg/ kg food.
[^{F15} 1068	2530-83-8-	(2,3-epoxypropoxy)propyl]trimethoxy silane	no	yes	no				Only to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinyl ester) in contact with all foodstuffs. In treated glass fibres, residues

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

								of the substance must not be detectable at 0,01 mg/kg for the substance and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).
[^{F25} 1069	75-28-5	isobutanes	yes	no	no			Only to be used as a blowing agent.
[^{F26} 1075		Montmorillonite clay modified with hexadecyltrimethylammonium bromide	no	no	no			Only to be used as additive at up to 4,0 % w/w in polylactic acid plastics intended for long-term storage

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

								of water at ambient temperature or below. Can form platelets in the nanoform that are in one or two dimensions thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.
1076		1227937	Phosphoric acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester	no	no	0,05		Only to be used as an additive at up to 0,2 % w/w in high impact polystyrene materials and articles intended

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

								contact with food at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III.	
1077			Titaniumdioxide surface-treated with fluoride-modified alumina	yes	no	no		Only to be used at up to 25,0 % w/w, including in the nanoform.	29]

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 [^{F4}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 [^{F5}[^{F6}Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total

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

diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).]

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 [^{F7}OJ L 83, 22.3.2012, p. 1 .]

i [^{F8}Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013.

j Young children as defined in Article 2(2)(b) of Regulation (EU) No 609/2013.]

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 \(Official Journal of the European Union L 338 of 12 December 2012\).](#)

Textual Amendments

F4 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 \(Text with EEA relevance\).](#)

F5 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 \(Text with EEA relevance\).](#)

F6 Substituted by [Commission Regulation \(EU\) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation \(EU\) No 10/2011 as regards the use of that substance in plastic food contact materials \(Text with EEA relevance\).](#)

F7 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 \(Text with EEA relevance\).](#)

F8 Inserted by [Commission Regulation \(EU\) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation \(EU\) No 10/2011 as regards the use of that substance in plastic food contact materials \(Text with EEA relevance\).](#)

F9 Deleted by [Commission Regulation \(EU\) 2017/752 of 28 April 2017 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

F10 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 \(Text with EEA relevance\).](#)

F11 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 \(Text with EEA relevance\).](#)

F12 Substituted by [Commission Regulation \(EU\) 2020/1245 of 2 September 2020 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 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 \(Text with EEA relevance\).](#)

F14 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 \(Text with EEA relevance\).](#)

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

- F15** Substituted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F16** 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).
- F17** Substituted by Commission Regulation (EU) 2018/831 of 5 June 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F18** 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).
- F19** Substituted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F20** 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).
- F21** 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).
- F22** Inserted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F23** Substituted by Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F24** Inserted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F25** Inserted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F26** Inserted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Textual Amendments

- F1** Word in [Annex 1](#) point 1 omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **76**; 2020 c. 1, Sch. 5 para. 1(1)

2. Group restriction of substances **U.K.**

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.

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

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

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

TABLE 2

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T)[mg/kg]	Group restriction specification
1	128 211	6	expressed as acetaldehyde
[^{F2} 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	0,006	expressed as tin

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

	466 582 618 619 620 646 676 736		
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
[^{F13} 14	294	5	expressed as the sum of the substances and their oxidation products
	368		
	894]		
[^{F10} 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

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

20	290 386 390	30	expressed as the sum of the substances
21	347 349	5	expressed as trimellitic acid
22	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	expressed as acrylic acid
23	150 156 181 183 184 355 370 374 439 440 447 457 482	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

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

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
[^{F10} 30	254 344 672	5	expressed as 1,4-butanediol]
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815	60	expressed as the sum of the substances
[^{F7} 33	180 874	ND	expressed as eugenol]
[^{F21} 34	421 988	0,05	Expressed as 1,3-benzenedimethanamine]
[^{F25} 35	467 744 1059	0,05	expressed as crotonic acid]

3. Notes on verification of compliance **U.K.**

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.

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

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)	(2)
Note No	Notes on verification of compliance
(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004.
[^{F11} (4)	Compliance testing when there is a fat contact [^{F2} shall] be performed using saturated fatty food simulants as simulant D2.]
(5)	Compliance testing when there is a fat contact [^{F2} 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.

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

(12)	There is a risk that the SML could be exceeded from polyolefins.
(13)	Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.
(14)	There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.
(15)	There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.
(16)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods
(17)	Only a method for determination of the residual content of the substance in the polymer is available
[^{F18} (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]
[^{F21} (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]
[^{F4} (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.]
[^{F20} (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

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

	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.]
[^{F22} (24)	The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified.]
[^{F24} (25)	When used as reheat agent in polyethylene terephthalate (PET) verification of compliance with the specific migration limit is not required; in all other cases compliance with the specific migration limit shall be verified in accordance with Article 18; the specific migration limit is expressed as mg tungsten/kg food.
(26)	Migration of stearamide, listed in Table 1 under FCM substance No 306 to which no specific migration limit applies, shall be excluded from verification of the compliance of the migration of the mixture with the specific migration limit laid down for the mixture.]
[^{F25} (27)	When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) 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.]
[^{F26} (28)	A detection limit of 0,002 mg/kg food or food simulant applies
(29)	In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under

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

contact conditions above 4 hours at 100 °C
this exceedance can be high.]

4. Detailed specification on substances **U.K.**

Table 4 on detailed specifications on substances contains the following information

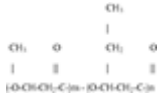
Column 1 (FCM substance No): contains the unique identification number of the substances referred to in Column 1 in Table 1 of Annex I to which the specification applies.

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

TABLE 4

(1)	(2)	
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,

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		stabilisers and pigments which all conform to the general and individual specifications
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	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-hydroxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids
	Description	White to off-white powder after isolation
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	[¹⁵ F]Restriction	Specific migration limit for crotonic acid is 0,05 mg/kg food]
	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

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

	— 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

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX I.