
Status: Point in time view as at 31/12/2020.

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

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

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ANNEX I

Substances

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

Table 1 contains the following information:

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

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

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

Column 4 (Substance Name): the chemical name

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

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

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

[^{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.

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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] (Group No)	SML (T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on certification of compliance
1	12310	0266309	albumin	no	yes	no				
2	12340	—	albumin coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols aliphatic, monohydric, saturated, 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)

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			(60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate						
5	25360	—	trialkyl (C ₉ -C ₁₅) acetic acid, 2,3-epoxypropyl ester	yes	no	ND		1 mg/kg in final product expressed as epoxy group. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	no	0,05		(1)
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			

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			(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			

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			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			

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			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-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	—	ethylhexyl mercaptoacetate	yes	no	no				
35	54280	—	ethylhexyl mercaptoacetate	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and	yes	no	no				

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			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				

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			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				

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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)		

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			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	—	polyethylene glycol diricinoleate	yes	42			
75	77702	—	polyethylene glycol esters of aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates	no				
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-	no	no	0,05		Only for use in PET

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			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(EO = 3-8) ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclic bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05			Not to be used for articles in contact with fatty foods for which [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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									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 0010191	codeine hydrochloride	yes	no	no			
111	53600	000006000-4	benzoin acid	yes	no	no			
112	64015	000006013-3	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	000006756-4	ethanol	no	yes	no			
118	23830	000006726-3	propanol	yes	yes	no			
	81882								
119	30295	000006764-0	ethane	yes	no	no			
120	49540	000006766-1	dimethyl 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

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128	10060	000007550740	50740	aldehyde	yes	no		(1)		
129	17020	000007552110	52110	benzene oxide	yes	no	ND		1 mg/kg in final product	(10)
130	26110	000007553540	53540	hydrochloride	yes	no	ND			(1)
131	48460	00000755137-6	5137-6	yes difluoroethane	no	no				
132	26140	000007553870	53870	hydro fluoride	yes	no	5			
133	14380	00000755446-23155	5446-23155	nylino chloride	yes	no	ND		1 mg/kg in final product	(10)
134	43680	000007554560	54560	chlorofluoromethane	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	00000774070	74070	butyl acetyl citrate	yes	no	no	(32)		
139	14680	000007744160	744160	acid	yes	yes	no			
	44160									
140	44640	00000774640	74640	acid, triethyl ester	yes	no	no	(32)		

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141	13380	0000077199-6	199-6-trimethylolpropane	yes	yes	no	6		
	25600								
	94960								
142	26305	0000078084-0	8084-0-trimethoxysilanes	no	no	no	0,05	Only to be used as a surface treatment agent	[^{F9} (1)]
143	62450	0000078178-4	8178-4-pentanes	yes	no	no			
144	19243	0000078279-5	8279-5-methyl-1,3-butadiene	no	yes	no	ND	1 mg/kg in final product	
	21640								
145	10630	0000079006-1	9006-1-amide	no	yes	no	ND		
146	23890	0000079009-1	9009-1-acid	yes	yes	no			
	82000								
147	10690	0000079021-0	9021-0-acrylic acid	no	yes	no		(22)	
148	14650	0000079118-9	9118-9-trifluoroethylene	no	no	no	ND		(1)
149	19990	0000079130-0	9130-0-acrylamide	yes	yes	no	ND		
150	20020	0000079141-0	9141-0-acrylic acid	yes	yes	no		(23)	
[^{F6} 151]	13480	0000080205-7	0205-7-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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										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	2,2,4,4-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088	2,6-aminobenzamide	yes	no	no	0,05			Only for use in PET for water and beverages

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165	23200	0000088	09-3	yes	yes	no				
	74480		phthalic acid							
166	24057	0000089	32-7	yes	yes	no	0,05			
			pyromellitic anhydride							
167	25240	0000091	208-7	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
			toluene diisocyanate							
168	13075	0000091	1276-9	no	yes	no	5			[F ⁹ (1)]
	15310		diamino-6-phenyl-1,3,5-triazine							
169	16240	0000091	1397-4	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
			dimethyl-4,4'-diisocyanatobiphenyl							
170	16000	0000092	2488-6	no	yes	no	6			
			dihydroxybiphenyl							
171	38080	0000093	3582-3	yes	no	no				
			benzoic acid, methyl ester							
172	37840	0000093	3582-3	yes	no	no				
			benzoic acid, ethyl ester							
173	60240	0000094	4413-3	yes	no	no				
			hydroxybenzoic acid, propyl ester							
174	14740	0000095	5648-7	no	yes	no				
			cresol							
175	20050	0000096	6051-9	yes	yes	no	0,05			
			methacrylic acid, allyl ester							

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

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	Benzoic acid	no	yes	no		(33)		
181	20890	000009762	Acrylic acid, ethyl ester	no	yes	no		(23)		
182	19270	000009765	Benzoic acid	no	yes	no				
183	21010	000009784	Acrylic acid, isobutyl ester	no	yes	no		(23)		
184	20110	000009788	Acrylic acid,	no	yes	no		(23)		

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			butyl ester						
185	20440	0000097	0015-methylacrylic acid, diester with ethyleneglycol	yes	no	0,05			
186	14020	0000098	45-4-butylphenol	no	yes	no	0,05		
187	22210	0000098	83-9-methylstyrene	no	yes	no	0,05		
188	19180	0000099	60-8-phthalic acid dichloride	yes	no		(27)		
189	60200	0000099	476-3 hydroxybenzoic acid, methyl ester	yes	no	no			
190	18880	0000099	96-7 hydroxybenzoic acid	no	yes	no			
191	24940	0000100	00-9-phthalic acid dichloride	yes	no		(28)		
192	23187	—	phthalic acid	no	yes	no	(28)		
193	24610	0000100	42-5-styrene	no	yes	no			
194	13150	0000100	51-7-benzyl alcohol	no	yes	no			
195	37360	0000100	52-7-benzaldehyde	no	no				(3)
196	18670	0000100	07-0-hexamethylenetetramine	no	no		(15)		
	59280								
197	20260	0000101	40-9-methylacrylic acid, cyclohexyl ester	yes	no	0,05			
198	16630	0000101	60-8-diphenylmethane, 4,4'-diisocyanate	no	no		(17)	1 mg/kg in final product expressed as	(10)

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									isocyanate moiety	
199	24073	00001021006	1,3-bis(4-cyclohexyldioxy)propane diglycidyl ether	yes	no	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	00001021081	1,3-bis(4-phenylthio)propane diphenylthiourea	yes	no	yes	3			
201	16540	00001021090	1,3-bis(4-phenyloxy)propane carbonate	no	yes	no	0,05			
202	23070	00001021336	1,3-bis(4-phenyloxy)propane diacetic acid	no	yes	no	0,05			[F ⁹ (1)]
203	13323	00001021449	1,3-bis(2-hydroxyethoxy)benzene	no	yes	no	0,05			
204	25180 92640	00001021603	1,3-bis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
205	25385	00001021705	1,3-bis(2-hydroxypropyl)ethylenediamine	yes	no	no			40 mg/kg hydrogel at a ratio of 1 kg food	

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									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-(4-hydroxyphenyl) acetamide	no	yes	no	0,05			
209	17050	0000104	4276-7 ethyl-1-hexanol	no	yes	no	30			
210	13390 14880	0000105	408-8 bis(hydroxymethyl)cyclohexane	no	yes	no				
211	23920	0000105	381-1 acrylic acid, vinyl ester	no	yes	no		(1)		
212	14200 41840	0000105	560-2 ε-caprolactam	no	yes	no		(4)		
213	82400	0000105	5162-4 propyleneglycol dioleate	yes	no	no				

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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	phenol	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	stearic acid	yes	no	no			
222	13870	0000106498-9	butene	no	yes	no			
223	13630	000010699-0	butadiene	no	yes	no	ND		1 mg/kg in final product
224	13900	0000107291-7	butene	no	yes	no			
225	12100	000010731-6	acrylonitrile	yes	no	no	ND		
226	15272	000010715-6	ethylenediamine	yes	no	no	12		
	16960								
227	16990	000010727-6	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	000010810-0	methylethylaminoethanol	yes	no	no	18		

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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	0000110141-0	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	0000110168-3	Hexane	no	yes	no	5		
256	18010	0000110194-0	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	0000111006-8	Sebacic acid, butyl ester	yes	no	no			
259	58720	0000111144-8	Heptanoic acid	yes	no	no			
260	24280	0000111206-0	Sebacic acid	no	yes	no			
261	15790	0000111401-0	1,4-bis(2-hydroxyethyl)ethanamine	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/

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									or D2] is laid down. For indirect food contact only, behind a PET layer.
263	13326	0000111466	1,4-hydroxyethyl 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	1,4-hydroxyethyl 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	1,4-hydroxyethyl glycol	yes	no				
	92350								
270	22763	0000112801	acid	yes	yes	no			
	69040								
271	52720	0000112845	amide	yes	no	no			
272	37040	0000112856	benzoic acid	yes	no	no			
273	52730	0000112867	acid	yes	no	no			
274	22570	0000112069	decyl isocyanate	no	yes	no	(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115007	polyene	no	yes	no			

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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	00001178	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)		

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			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 phthalic acid, dimethyl ester	yes	no				
289	15880	0000120	182-9 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	10-3 propylamine	yes	no	no	5		
293	23175	0000122	52 phosphorus acid, triethyl ester	yes	no	no	ND		1 mg/kg in final product (1)
294	93120	0000123	28-11 dodecyl propionic acid, didodecyl ester	yes	no	yes		(14)	
295	15940	0000123	14-9 dihydroxybenzene	yes	yes	no	0,6		
	18867								
	48620								
296	23860	0000123	38-6 formaldehyde	yes	no	no			
297	23950	0000123	60-6 phthalic anhydride	no	yes	no			
298	14110	0000123	72-8 benzaldehyde	yes	no	no			
299	63840	0000123	76-11 salicylic acid	yes	no	no			
300	30045	0000123	86-14 butyl acrylate	yes	no	no			

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301	89120	0000123805-5	sebacic acid, butyl ester	yes	no	no			
302	12820	0000123829-6	acetic acid	no	yes	no			
303	12130	0000124044-9	adipic acid	yes	yes	no			
	31730								
304	14320	0000124072-2	glycolic acid	yes	yes	no			
	41960								
305	15274	0000124094-4	methylenedianiline	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	acetate isobutyrate	yes	no	no			
309	91360	0000126347-7	octaacetate	yes	no	no			
310	16390	0000126230-7	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	0000128236-0	tert-butyl-p-cresol	yes	no	no	3		
316	23230	0000131719-1	phthalic acid, diallyl ester	no	yes	no	ND		

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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	822-7 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 fatty acid	yes	no	yes	42			
325	10780	000014	122-1 fatty 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.

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										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	000014310-7	lactic acid	yes	yes	no				
	63280									
331	22480	000014310-8	nonanol	no	yes	no				
332	69760	000014328-2	alcohol	yes	no	no				
333	22775	000014462-1	lactic acid	yes	yes	no	6			
	69920									
334	17005	000015156-4	benzidine	yes	no	no	ND			
335	68960	000030102-0	amide	yes	no	no				
336	15095	000033448-5	decanoic acid	yes	yes	no				
	45940									
337	15820	000034549-6	difluorobenzophenone	no	yes	no	0,05			
338	71020	000037349-0	lactic acid	yes	no	no				
339	86160	000040951-0	silicon carbide	yes	no	no				
[^{F14} 340	47440	000046158-5	dianhydride	no	no	no	60]			
341	13180	000049866-8	hept-2-ene	no	no	no	0,05			
	22550									
342	14260	000050244-3	lactone	yes	no	no		(29)		
343	23770	000050413-2	propanediol	no	yes	no	0,05			

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F10 344	13810	0000505165-7 butanediol formal	no	yes	no	0,05	15 30		(21)
	21821]								
345	35840	000050630-9 maleic acid	yes	no	no				
346	10030	000051410-6 maleic acid	no	yes	no				
347	13050	000052841-9 maleic acid	no	yes	no		(21)		
	25540								
348	22350	000054463-8 maleic acid	yes	yes	no				
	67891								
349	25550	000055241-7 maleic anhydride	no	yes	no		(21)		
350	63920	000055759-5 maleic acid	yes	no	no				
351	21730	0000563345-1 methyl-1-butene	no	yes	no	ND		Only to be used in polypropylene	(1)
352	16360	000057626-1 dimethylphenol	no	yes	no	0,05			
353	42480	000058408-8 maleic 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	000058507-9 acrylic acid, tert-butyl ester	yes	yes	no		(23)		
356	18820	0000592441-6 hexene	no	yes	no	3			
357	13932	0000598332-3 buten-2-ol	no	yes	no	ND		Only to be used	(1)

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									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 triheptanoate	no	no					
361	18700	000062911-8	no hexanediol	yes	no	0,05				
362	14350	000063088-0	no 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)	a co- monomer in poly(ethylene- co- isosorbide terephthalate); (b)	a co- monomer at levels of up to 40 mole % of the diol component in

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									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-oxydodecanoic acid, isopropyl ester	no	yes	no		(22)	
366	22150	0000691	437-2-methyl-1-pentene	no	yes	no	0,05		
367	16697	0000693	23-2-dodecanedioic acid	no	yes	no			
368	93280	0000693	16-7-propionic acid, dioctadecyl ester	no	yes	no		(14)	

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369	12761	0000693	127-2	no	yes	no	0,05			
			aminododecanoic acid							
370	21460	0000760	093-10	no	yes	no		(23)		
			acrylic anhydride							
371	11510	0000818	61-11	no	yes	no		(22)		
	11830		acrylic acid, monoester with ethyleneglycol							
372	18640	0000822	206-0	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
			hexamethylene diisocyanate							
373	22390	0000840	266-3	no	yes	no	0,05			
			naphthalenedicarboxylic acid, dimethyl ester							
374	21190	0000868	77-10	no	yes	no		(23)		
			acrylic acid, monoester with ethyleneglycol							
375	15130	0000872	2405-9	no	yes	no	0,05			
			decene							
[^{F13} 376	66905	0000872	250-4	yes	no	no	60]			
			methylpyrrolidone							
377	12786	0000919	330-2	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	
			aminopropyltriethoxysilane							

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										treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles.
378	21970	0000923	202-4 methylmethacrylamide	no	yes	no	0,05			
379	21940	0000924	42-5 methylolacrylamide	no	yes	no	ND			
380	11980	0000925	66-1 acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931	81-4 dioctane	yes	no	no	0,05			Only to be used in polymers contacting foods for which simulant A is laid down
382	19490	0000947	04-6 lactam	yes	no	no	5			
383	72160	0000948	265-2 phenylindole	yes	no	yes	15			
384	40000	0000991	284-4 bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			

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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	gallic 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 gallic 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:	

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									—	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	6,6,10-trimethyl-2-hydroxy	yes	no	no				
395	41520	0001305	7,8,8-trimethyl-1-oxido	yes	no	no				
396	64640	0001309	4,4'-bis(2-hydroxyphenyl)	yes	no	no				
397	64720	0001309	4,4'-bis(2-oxidophenyl)	yes	no	no				
[^{F12} 398	35760	0001309	4,4'-dithionyltrioxide	yes	no	no				(6)]
399	81600	0001310	5,8,8-trimethyl-3-hydroxy	yes	no	no				

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400	86720	0001310571-2	zinc hydroxide	yes	no	no			
401	24475	0001313821-2	zinc sulphide	no	yes	no			
402	96240	0001314211-2	zinc oxide	yes	no	no			
403	96320	0001314281-3	zinc sulphide	yes	no	no			
404	67200	0001317331-5	zinc disulphide	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	0001330541-4	sodium tetraborate	yes	no	no		(16)	
408	82960	0001330181-9	propyleneglycol monooleate	yes	no	no			
409	62240	0001332151-2	zinc oxide	yes	no	no			
[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

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									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

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									2,5 % w/w.
412	45200	0001335	50-20-05 Copper iodide	yes	no	no		(6)	
413	35600	0001336	21-16-01 Cadmium hydroxide	yes	no	no			
414	87600	0001338	30-12-01 Sorbitan monolaurate	yes	no	no			
415	87840	0001338	30-12-01 Sorbitan monostearate	yes	no	no			
416	87680	0001338	30-12-01 Sorbitan monooleate	yes	no	no			
417	85680	0001343	18-02-01 Sulfuric acid	yes	no	no			
418	34720	0001344	28-09-01 Zinc oxide	yes	no	no			
419	92150	0001401	15-01-01 Fatty acids	yes	no	no			According to the JECFA specifications
420	19210	0001459	03-03-01 Phthalic acid, dimethyl ester	no	yes	no	0,05		
[^{F14} 421	13000	0001477	15-01-01 Benzene dimethanamine	no	yes	no		(34)]	
422	38515	0001533	34-05-01 Bis(2- benzoxazolyl) stilbene	yes	no	yes	0,05		(2)
423	22937	0001623	05-08-01 Propyl ether	no	yes	no	0,05		
424	15070	0001647	16-01-01 Decadiene	no	yes	no	0,05		
425	10840	0001663	03-04-01 Acrylic acid, tert- butyl ester	no	yes	no		(22)	
426	13510	0001675	21-03-01 Bis(4- hydroxyphenyl) propane	no	yes	no			In compliance with Commission Regulation (EC)
	13610		21-03-01 Bis(2,3- epoxypropyl) ether						

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								No 1895/2005 ^a	
427	18896	0001679451-2	(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05		
428	95200	0001709170-52	trimethyl-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	0002082703-3	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6		
434	20410	0002082847-1	acrylic acid, diester with 1,4-butanediol	yes	yes	no	0,05		
435	14230	0002123241-2	lactam, sodium salt	yes	yes	no		(4)	
436	19480	0002146171-6	acid, vinyl ester	no	yes	no			
437	11245	0002156407-1	ic acid,	no	yes	no	0,05		(2)

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			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
439	21280	0002177701	methacrylic acid, phenyl ester	no	yes	no		(23)	
440	21340	0002210281	methacrylic acid, propyl ester	no	yes	no		(23)	
441	38160	0002315682	maleic acid, propyl ester	no	yes	no			
442	13780	0002425174	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	aminoundecanoic acid	no	yes	no	5		
444	61440	0002440222	4-hydroxy-5'-methylphenyl)benzotriazole	no	yes	no		(12)	
445	83440	0002466093	phosphoric acid	no	no	no			

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446	10750	0002495	35-46 acrylic acid, benzyl ester	no	yes	no		(22)		
447	20080	0002495	35-46 acrylic acid, benzyl ester	yes	yes	no		(23)		
448	11890	0002499	50-46 acrylic acid, n-octyl ester	no	yes	no		(22)		
[^{F11} 449	49840	0002500	48-46 cyclohexane disulphide	no	yes	yes	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 acrylic acid, 2- (dimethylamino)- ethyl ester	yes	yes	no	ND			
456	10810	0002998	08-46 acrylic acid, sec-	no	yes	no		(22)		

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			butyl ester						
457	20140	0002998	1817-81-8 acrylic acid, sec-butyl ester	yes	no		(23)		
458	36960	0003061	75-4 benzamide	no	no				
459	46870	0003135	318-01-8 tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no				
460	14950	0003173	5313-60-1 hexamethylene diisocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
461	22420	0003173	3472-6 naphthalene diisocyanate	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	3762-8-1 naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no			

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466	50640	0003648	18-8 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	29 21 hydroxy-3,5'- di-tert- butylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896	21 25 hydroxy-3'- tert- butyl-5'- methylphenyl)-5- chlorobenzotriazole	yes	no	yes		(12)		
471	24888	0003965	55 57 sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066	27 28 methylenebis(4- methyl-6- cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074	40 42 acid, divinyl ester	no	yes	no	ND		5 mg/ kg in final product. Only to be used as co- monomer.	(1)
474	43600	0004080	43 33 chloroallyl)-3,5,7-	yes	no	no	0,3			

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			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 adipic 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)		

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			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	30-1 diisocyanate	no	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
486	54005	0005136	44-7 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	18-3 ethylenebispalmitamide	yes	no	no				
489	41040	0005743	36-2 butyrate	yes	no	no				
490	16600	0005873	54-1 diisocyanate	no	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	0006182	11-2 propyleneglycol distearate	yes	no	no				
492	45650	0006197	230-4 cyano-3,3-diphenylacrylic acid, 2-	yes	no	no	0,05			

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			ethylhexyl ester							
493	39200	000620064024	(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	yes	no	no	1,8			
494	62140	00063032705	phosphorous acid	no	no	no				
495	35160	0006642631-5	amino-1,3-dimethyluracil	yes	no	no	5			
496	71680	00066839118	erythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	no	no	no				
497	95020	00068462504	trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5			Only to be used in single-use gloves
498	16210	0006864337-5	dimethyl-4,4'-diaminodicyclohexylmethane	no	yes	no	0,05			Only to be used in polyamides (5)
499	19965 65020	00069151117	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

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									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)		

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506	86920	0007632s00i0m	nitrite	yes	no	no	0,6			
507	59990	0007647h01h0	chloric acid	yes	no	no				
508	86560	0007647s0i0m	bromide	yes	no	no				
509	23170	0007664p08p	phosphoric acid	yes	yes	no				
	72640									
510	12789	0007664a11m7	ammonia	yes	yes	no				
	35320									
511	91920	0007664s0p0	peroxy acid	yes	no	no				
512	81680	0007681p01a6	potassium iodide	yes	no	no		(6)		
513	86800	0007681s02i0m	iodide	yes	no	no		(6)		
514	91840	0007704s01p0	sulphur	yes	no	no				
515	26360	0007732w01e5	water	yes	yes	no			In compliance with Directive 98/83/EC ^b	
	95855									
516	86960	0007757s01i7m	sulphite	yes	no	no		(19)		
517	81520	0007758s02a3i0m	potassium bromide	yes	no	no				
518	35845	0007771a01e0i0m	maleic acid	yes	no	no				
519	87120	0007772s01i7m	thiosulphate	yes	no	no		(19)		
520	65120	0007773p01a05	manganese chloride	yes	no	no				
521	58320	0007782s01a5	zinc white	yes	no	no				
522	14530	0007782s01i05	zinc white	no	yes	no				
523	45195	0007787e00p0	copper bromide	yes	no	no				
524	24520	0008001s02b7	can oil	no	yes	no				
525	62640	0008001j01a6	Japan wax	yes	no	no				

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526	43440	0008001	le 7561	yes	no	no				
527	14411	0008001	le 794	yes	yes	no				
	42880		oil							
528	63760	0008002	le 435	yes	no	no				
529	67850	0008002	le 507	yes	no	no				
530	41760	0008006	le 448	yes	no	no				
531	36880	0008012	le 893	yes	no	no				
532	88640	0008013	le 078	yes	no	no	60 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined

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										by Directive 2006/125/ EC, the SML is lowered to mg/30 kg.
533	42720	0008015869	Sebacic wax	yes	no	no				Oxirane < 8 %, iodine number < 6.
534	80720	0008017067	phosphoric acids	yes	no	no				
535	24100	0008050097	Oronit	yes	yes	no				
	24130									
	24190									
	83840									
536	84320	0008050456	hydrogenated, ester with methanol	yes	no	no				
537	84080	0008050268	ester with pentaerythritol	yes	no	no				
538	84000	0008050316	ester with glycerol	yes	no	no				
539	24160	0008052406	tall oil	no	yes	no				
540	63940	0008062156	sulphonic acid	yes	no	no	0,24			Only to be used as dispersant for plastics dispersions

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541	58480	0009000g01h5	gum arabic	yes	no	no				
542	42640	0009000e11b7	methylcellulose	yes	no	no				
543	45920	0009000d16h2	har	yes	no	no				
544	58400	0009000g31a0	gum	yes	no	no				
545	93680	0009000t65a0	alginate gum	yes	no	no				
546	71440	0009000p60t1	pe	yes	no	no				
547	55440	0009000g71a8	gum	yes	no	no				
548	42800	0009000e11e1	cellulose	yes	no	no				
549	80000	0009002p88e4	polyethylene wax	yes	no	no				
550	81060	0009003p07e0	propylene wax	yes	no	no				
551	79920	0009003p01e6 0106392	poly(ethylene glycol)	yes	no	no				
552	81500	0009003p09e8	polyvinylpyrrolidone	yes	no	no				The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC ^c
553	14500	0009004e31h1	cellulose	yes	yes	no				
	43280									
554	43300	0009004e31h8	cellulose acetate butyrate	yes	no	no				
555	53280	0009004e17h1	cellulose	yes	no	no				
556	54260	0009004e18h4	hydroxyethylcellulose	yes	no	no				
557	66640	0009004e50h5	ethylcellulose	yes	no	no				
558	60560	0009004h21e0	hydroxyethylcellulose	yes	no	no				
559	61680	0009004h41e2	hydroxypropylcellulose	yes	no	no				

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560	66700	000900446513	hydroxypropylcellulose	yes	no	no			
561	66240	000900446515	cellulose	no	no	no			
562	22450	000900447000	cellulose	yes	no	no			
563	78320	000900449714	polyethylene glycol monoricinoleate	yes	no	yes	42		
564	24540	000900552588	starch, edible	yes	yes	no			
	88800								
565	61120	000900552710	hydroxyethyl starch	yes	no	no			
566	33350	000900552917	alginate acid	yes	no	no			
567	82080	000900554372	propyleneglycol alginate	yes	no	no			
568	79040	000900560456	polyethylene glycol sorbitan monolaurate	yes	no	no			
569	79120	000900560566	polyethylene glycol sorbitan monooleate	yes	no	no			
570	79200	000900560677	polyethylene glycol sorbitan monopalmitate	yes	no	no			
571	79280	000900560788	polyethylene glycol sorbitan monostearate	yes	no	no			
572	79360	000900560923	polyethylene glycol sorbitan trioleate	yes	no	no			
573	79440	000900561044	polyethylene glycol sorbitan tristearate	yes	no	no			
574	24250	000900604466	orbiter, natural	yes	yes	no			
	84560								
575	76721	006314860299	dimethylsiloxane (Mw > 6 800 Da)	yes	no	no			Viscosity at 25 °C not less than 100 cSt (100 ×

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									10 ⁻⁶ m ² /s)
576	60880	00090324	hydroxyethylmethylcellulose	yes	no	no			
577	62280	00090441	isobutylene-butene copolymer	yes	no	no			
578	79600	00090460	polyethylene glycol 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)	

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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	lead(II) hypophosphite	yes	no	no				
587	68400	00100944	lecithin	yes	yes	no	5			
588	64320	00103771	lithium iodide	yes	no	no		(6)		
589	52645	00104360	18-1-eicosenamide	yes	no	no				
590	21370	00105958	methacrylic acid, 2-sulphoethyl ester	yes	no	no	ND			(1)
591	36160	00106058	myristyl stearate	yes	no	no				
592	34690	00110975	nickel magnesium carbonate hydroxide	yes	no	no				
593	44960	00111046	nickel oxide	yes	no	no				
594	65360	00111296	nickel(II) oxide	yes	no	no				
595	19510	00111321	nicotinic acid	yes	no	no				
596	95935	00111386	nicotinic acid gum	yes	no	no				
597	67120	00120011	nickel(II) chloride	yes	no	no				
598	41600	00120041	nickel(II) sulphate	yes	no	no				
		00372935	nickel(II) sulphate	yes	no	no				
599	36840	00120075	nickel(II) tetraborate	yes	no	no		(16)		
600	60030	00120725	nickel(II) hydroxide	yes	no	no				
601	35440	00121247	nickel(II) bromide	yes	no	no				
602	70240	00121989	nickel(II) chloride	yes	no	no				
603	83460	00122697	nickel(II) pyrophosphate	yes	no	no				

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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	yes	no	no			
607	62245	001275120-3	Iron-3 phosphide	yes	no	no			Only to be used in PET polymers and copolymers
608	40800	001300342-8	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	no			
614	45560	001446465-0	Hydrolytic	no	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		

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

			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		

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			ethyl ester						
633	53200	0023949266-8	ethoxy-2'-ethyloxanilide	yes	no	yes	30		
634	25910	002480044-0	propylene glycols			no			
635	40720	002501346-5	butyl-4-hydroxyanisole	yes	no	no	30		
636	31500	002513451-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester
637	71635	002515196-6	polybutylene terephthalate		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
638	23590	002532268-3	polyethylene glycols			no			
	76960								
639	23651	002532269-4	polypropylene glycol			no			
	80800								
640	54930	002535960-1	formaldehyde-naphthol, copolymer		no	no	0,05		
[F ² 641	22331	002551364-8	copolymer of (35-45 % w/w) 1,6-	no	yes	no	0,05]		

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			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 monoheptanoate	yes	no	no			
648	56880	0026402	2366 monoheptanoate	yes	no	no			
649	47210	0026427	4076 ethylthiostannonic acid polymer	no	no	no			Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)
650	49600	0026636	0111 bis(isooctyl mercaptoacetate)	yes	no	no	(9)		

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663	64150	002829017011	oleic acid	yes	no	no			
664	95000	0028931671	trimethyl methacrylate-methyl methacrylate copolymer	no	no				
665	83120	0029013128-3	propyleneglycol monopalmitate	yes	no	no			
666	87280	0029116508	sebacic diolate	yes	no	no			
667	55190	0029204021	oleic acid	yes	no	no			
668	80240	0029894357	polyglycerol ricinoleate	yes	no	no			
669	56610	0030233648	glycerol monobehenate	yes	no	no			
670	56800	0030899628	glycerol monolaurate diacetate	yes	no	no	(32)		
671	74240	0031570044	phosphoric acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no			
672	76845	0031831515	polyester of 1,4-butanediol with caprolactone	yes	no	no	(29) (30)	The fraction with molecular weight below 1 000 Da [F ² shall] not exceed 0,5 % (w/w)	
673	53670	0032509661	glycerol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6		

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674	46480	0032647	467-9 bisphenol sorbitol	no	no				
675	38800	0032687	718-8 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	682-2 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	yes	no			
683	66200	0037206	605-2 methylcarboxymethylcellulose	yes	yes	no			
684	68125	0037244	606-1 ephaline syenite	yes	no	no			
685	85950	0037296	472-2 acid, magnesium- sodium- fluoride salt	yes	no	no	0,15		SML expressed as fluoride. Only to be used

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										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	bis(3,4-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		

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693	88160	005414030614	sofitan 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	005756940	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	006116758	phthalic acid, 2-tert- butyl-6- (3-tert- butyl-2- hydroxy-5- methylbenzyl)-4- methylphenyl ester	yes	no	yes	6		
701	40160	006126961	N,N2 bis(2,2,6,6- tetramethyl-4- piperidyl)hexamethylenediamine-1,2- dibromoethane, copolymer	yes	no	no	2,4		
702	87920	006175268	sofitan yes tetrastearate	no	no				
703	17170	006178887	fatty acids, coco	no	yes	no			

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704	77600	0061788	85-014 polyethylene glycol ester of hydrogenated castor oil	yes	no	no			
705	10599/91	0061788	88-014 fatty, unsaturated (C ₁₈), dimers, non hydrogenated, distilled and non- distilled	no	yes	no		(18)	(1)
706	17230	0061790	12-3 fatty acids, tall oil	no	yes	no			
707	46375	0061790	53-2 stannous earth	yes	no	no			
708	77520	0061791	12-6 polyethylene glycol ester of castor oil	yes	no	no	42		
709	87520	0062568	11-0 stibitan monobehenate	yes	no	no			
710	38700	0063397	66-2 bis(2- carbutoxyethyl) tin- bis(isooctyl mercaptoacetate)	yes	no	yes	18		
711	42000	0063438	80-2 tris(2- carbutoxyethyl) tin- tris(isooctyl mercaptoacetate)	yes	no	yes	30		
712	42960	0064147	46-6 castor oil, dehydrated	yes	no	no			
[^{F10} 713	43480	0064365	44-0 charcoal activated	yes	no	no			Only for use in PET at maximum 10 mg/ kg of polymer.

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									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	0064365	10519 hydrogenated, ester with pentaerythritol	yes	no	no			
715	46880	0065140	391-01 tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6		
716	60800	0065447	172-0 hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30		
717	84210	0065997	10611 hydrogenated	yes	no	no			

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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	70-2 starch, hydrolysed starch, hydrogenated	no	yes	no			In compliance with the purity criteria for maltitol

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

									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	2-8-1 Fluorescein regenerated	yes	no	no				
728	75100	0068515 0028553	4-10 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

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

									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

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

		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

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										to 0,1 % in the final product.
730	66930	0068554	7011	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	no	no	no				
736	50960	0069226	414-4	yes	no	no		(10)		
737	77370	0070142	2046	yes	no	no				
738	60320	0070321	2812-7	yes	no	yes	1,5			

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			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	007187860986	[(1,1,3,3-tetramethylbutyl)amino]-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 83610	0073138836	acids and rosin acids	yes	yes	no			
742	92700	0078301242	4-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5		
743	38950	0079072596	4-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

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

									the specifications mentioned in the Table 4 of Annex I.]
745	68145	0080410233	2,2',3,3'-nitri(triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite)	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
746	38810	0080693600	2,2,4,4-tetra-tert-butyl-1,3-dimethylphenyl)diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
747	47600	0084030461	1,5-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)	
748	12765	0084434128	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05		
749	66360	0085209221	2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5		
750	66350	0085209223	2,2'-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5		
751	81515	0087189261	2,5-bis(zinc glycerolate)	yes	no	no			

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752	39890	008782644-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(methylenebisphenol)carbonate	yes	no	no			
753	62800	009270440-1	kaolin, calcined	yes	no	no			
754	56020	009988064-6	polyester dibehenate	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	lithium salt reaction product with citric acid, lithium salt	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	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 (*)),

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		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 (*)),

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									—	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(4-ethoxycarbonyl-2,6-dimethyl-1,4-	no	no	6				

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			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	33-3 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	24-5 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			

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			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(4-(2,4-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05		

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771	34650	0151841	55-11-yes bis(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 bis(2,4-dicumylphenyl)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	78-8-yes cyclohexanedicarboxylic acid, diisononyl ester	no	no		(32)		
776	76723	0167883	31-11-yes polydimethylsiloxane, 3-aminopropyl terminated,	no	no				The fraction with molecular

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			polymer with dicyclohexylmethane-4,4'-diisocyanate					weight below 1 000 Da [F ² shall not exceed 1,5 % (w/w)]	
777	31542	0174254	23-lytic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters	yes	no	no		0,5 % (1) in final product	
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	64-7 [[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-hexanediy][(2,2,6,6-tetramethyl-4-piperidiny)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-	yes	no	no	5		

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			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)	

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786	14627	0000117	321-5 chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3- chlorophthalic acid	
787	14628	0000118	445-6 chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4- chlorophthalic acid	
788	21498	0002530	185-0 (methacryloxy)propyltrimethoxysilane	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	10786- 1487 1,3,5- triazine-2,4- diyl)- [(2,2,6,6- tetramethyl-4- piperidyl)imino]]	yes	no	no	5		Average (16) molecular weight not less than	

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			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	3,5'- 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

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									hydrolysis products
793	94000	00001026	triethanolamine	no	no	0,05			SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine
[^{F13} 794	18117	00000794	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

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									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	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)]		
798	92200	0006422	terephthalic acid, 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	

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									(EU) No 231/2012. I	
800	94425	0000867	trihydroxy 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)

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									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.

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									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.
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
810	68119		neopentyl glycol, diesters and	yes	no	no	5	(32)	Not to be used for

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			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		

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			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	

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									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	

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			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	

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										time. I
857	66765	0037953	(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

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								methid tautomer.
[^{F4} 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

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								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	2395 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	2396 perfluoropoly- (n-propoxy)propanoic acid]	no	no			Only to be used in the polymerisation of fluoropolymers that are

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									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

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									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	
[FII] 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	

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										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 %	I
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 %	
I ¹¹ 868	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	

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											a maximum level of 5 % w/w; polyethylene terephthalate (PET) at a maximum level of 5 % w/w. I
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	01605354016	95500 N,N'-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide	yes	no	no	5				
[^{F20} 871		02879168043	871 68043 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)]

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			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		0006607241-6	phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	no	yes	no	0,05	To be used only as a co-monomer in polycarbonate copolymers	(20)]
[^{F18} 873	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no		Reaction product of titanium dioxide	

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									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			

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			and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C ₃ -C ₂₂)						
879	31336	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C ₁ -C ₂₂)	yes	no	no			
[^{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

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										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	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	

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884	34240	0091082	alkyl-C ₂₁ sulphonic acid, esters with phenol	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which [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

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									term storage at room temperature.
[F18]	894	93360	0016545516	5- <i>n</i> -propionic acid, ditetradecyl ester	no	no		(14)	
	895	47060	0171090393	5-(di- <i>tert</i> -butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols	yes	no	no	0,05	Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products.
	896	71958	0958445341	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

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									up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles.
[^{F7} 902		000012844-9	benzothiazolone 1,1-dioxide, sodium salt	yes	no	no			The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU) No 231/2012 " .]
[^{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

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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	yes	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	yes	no	no			Only to be used in the polymerisation of fluoropolymers	

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								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)

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									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	(98-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

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

									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]

Status: Point in time view as at 31/12/2020.

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

I ^{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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Status: Point in time view as at 31/12/2020.

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

									The 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(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]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-

Status: Point in time view as at 31/12/2020.

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

									The final material shall be used at room temperature or below.	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	

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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 58-95-7	62 tocopherol acetate	yes	no	no				Only to be used as antioxidant in polyolefins.	(24)
[^{F23} 1059	147398- 10	Pb (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)]

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

									food 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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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	1547-262	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

Status: Point in time view as at 31/12/2020.

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

								30 mg/ kg.	
1064		39318-18-8	Substituted oxides	yes	no	no	0,05	Stoichiometry: WO _n , n = 2,72-2,90	(25)
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	

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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 vinylester) in contact with all foodstuffs. In treated glass fibres, residues

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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). I
[^{F25} 1069	75-28-5	isobutane	yes	no	no			Only to be used as a blowing agent. I
[^{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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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-hydroxy poly[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	

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (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 \(Text with EEA relevance\).](#)

Status: Point in time view as at 31/12/2020.

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

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.

Status: Point in time view as at 31/12/2020.

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

Column 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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

Status: Point in time view as at 31/12/2020.

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

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.

Status: Point in time view as at 31/12/2020.

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

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

TABLE 3

(1) Note No	(2) Notes on verification of compliance
(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004.
[^{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.

Status: Point in time view as at 31/12/2020.

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

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

	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

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

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

4. Detailed specification on substances

Table 4 on detailed specifications on substances contains the following information

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

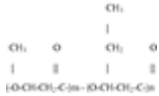
Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

(1)	(2)	
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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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

		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-hydro-xybutanoic 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
	[^{F15} 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

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

	— 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

[^{F12}ANNEX II

Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4).

Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

Table 1

General list of migration limits for substances migrating from plastic materials and articles

(1)	(2)	(3)	(4)
Name	Salts allowed in accordance with Article 6(3)(a)	SML [mg/kg food or food simulant]	Remark
Aluminium	yes	1	
Ammonium	yes		(1)
Antimony	no	0,04	(2)
Arsenic	no	ND	
Barium	yes	1	
Cadmium	no	ND (LOD 0,002)	
Calcium	yes		(1)
Chromium	no	ND	(3)
Cobalt	yes	0,05	
Copper	yes	5	
Europium	yes	0,05	(4)
Gadolinium	yes	0,05	(4)
Iron	yes	48	

Status: Point in time view as at 31/12/2020.

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

Table 1

General list of migration limits for substances migrating from plastic materials and articles

Lanthanum	yes	0,05	(4)
Lead	no	ND	
Lithium	yes	0,6	
Magnesium	yes		(1)
Manganese	yes	0,6	
Mercury	no	ND	
Nickel	no	0,02	
Potassium	yes		(1)
Sodium	yes		(1)
Terbium	yes	0,05	(4)
Zinc	yes	5	

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection.

Remarks

(1) The migration is subject to Article 11(3) and Article 12

(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3) To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:

- (a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and
- (b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁾ and for which no migration limit is specified in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/kg in food or food simulant.]

Status: Point in time view as at 31/12/2020.

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

ANNEX III

Food simulants

1. Food simulants

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

^[F2]TABLE 1

List of food simulants

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

2. General assignment of food simulants to foods

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

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

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

^[F23] Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

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

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

Table 2 contains the following information:

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

Status: Point in time view as at 31/12/2020.

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

- Column 2 (Description of food): contains a description of the foods covered by the food category
- Column 3 (Food simulants): contains sub-columns for each of the food simulants

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

For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4,5.

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

TABLE 2

food category specific assignment of food simulants

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

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

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

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

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

Status: Point in time view as at 31/12/2020.

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

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

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

		on the surface					
	II.	Other					X
	B.	In paste form:					
	I.	With fatty substances on the surface				X/2	
	II.	Moist		X			
03.03		Sugar and sugar products					
	A.	In solid form: crystal or powder					X
	B.	X Molasses, sugar syrups, honey and the like					
04		Fruit, vegetables and products thereof					
[^{F2} 04.01		Fruit, fresh or chilled:					
	A.	unpeeled and uncut					X/10

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

	B.	X peeled and/ or cut	X (*)				I
04.02	Processed fruit:						
	A.	Dried or dehydrated fruits, whole, sliced, flour or powder					X
	B.	Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)	X(*)	X			
	C.	Fruit preserved in a liquid medium:					
	I.	In an				X	

Status: Point in time view as at 31/12/2020.

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

		oily medium					
	II.	In an alcoholic medium			X		
04.03		Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):					
	A.	Shelled, dried, flaked or powdered					X
	B.	Shelled and roasted					X
	C.	X In paste or cream form				X	
[^{F2} 04.04		Vegetables, fresh or chilled:					
	A.	unpeeled and uncut					X/10
	B.	X peeled and/or cut	X (*)				1
[^{F2} 04.05		Processed vegetables:					
	A.	Dried or dehydrated					X

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

	vegetables whole, sliced or in the form of flour or powder.					
	B. (obsolete)					
	C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine).	X (*)	X			
	D. Preserved vegetables:					
	I. X In an oily medium				X	
	II. In an alcoholic medium			X		I
05	Fats and oils					
05.01	Animals and vegetable fats and				X	

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

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

Status: Point in time view as at 31/12/2020.

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

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

Status: Point in time view as at 31/12/2020.

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

		and other) or in the form of paste, creams					
	C.	X Marinated meat products in an oily medium				X	
06.04	Preserved meat:						
	A.	X In an fatty or oily medium				X/3	
	B.	In an aqueous medium	X(*)		X		
06.05	Whole eggs, egg yolk, egg white						
	A.	Powdered or dried or frozen					X
	B.	Liquid and cooked			X		
07	Milk products						
07.01	Milk						

Status: Point in time view as at 31/12/2020.

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

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

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

	rind (gouda, camembert, and the like) and melting cheese					
	C. Processed cheese (soft cheese, cottage cheese and similar)	X(*)		X		
	D. Preserved cheese:					
	I. X In an oily medium				X	
	II. In an aqueous medium (feta, mozzarella, and similar)	X(*)		X		
08	Miscellaneous products					
08.01	Vinegar	X				
08.02	Fried or roasted foods:					
	A. X Fried potatoes, fritters and the like				X/5	

Status: Point in time view as at 31/12/2020.

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

	B.	X Of animal origin				X/4	
08.03		Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents					
	A.	Powdered or dried:					
	I.	With fatty character				X/5	
	II.	Other					X
	B.	any other form than powdered or dried:					
	I.	X With fatty character	X(*)			X/3	
	II.	Other	X(*)	X			
08.04		Sauces:					

Status: Point in time view as at 31/12/2020.

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

	A.	With aqueous character	X(*)	X			
	B.	X With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces	X(*)			X	
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A.	X With fatty substances on the surface				X/5	
	B.	Other					X

Status: Point in time view as at 31/12/2020.

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

08.07	Ice-creams			X			
08.08	Dried foods:						
	A. With fatty substances on the surface					X/5	
	B. Other						X
08.09	Frozen or deep-frozen foods						X
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.		X(*)		X		
08.11	Cocoa:						
	A. Cocoa powder, including fat-reduced and highly fat reduced						X
	B. Cocoa paste					X/3	
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes,						X

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

	granulated or powdered						
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom and others						X
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other						X
08.15	Spices and seasoning in oily medium such as pesto, curry paste					X	

[^{F27}4. Food simulant assignment for testing overall migration

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

TABLE 3

Food simulant assignment for demonstrating compliance with the overall migration limit

Status: Point in time view as at 31/12/2020.

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

Foods covered	Food simulants in which testing shall be performed
all types of food	<ol style="list-style-type: none"> 1. distilled water or water of equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2.
all types of food except for acidic foods	<ol style="list-style-type: none"> 1. distilled water or water of equivalent quality or food simulant A; and 2. food simulant D2.
[^{F15} all aqueous and alcoholic foods and milk products with a pH \geq 4,5	food simulant D1
all aqueous and alcoholic foods and milk products with a pH < 4,5	food simulant D1 and food simulant B]
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	<ol style="list-style-type: none"> 1. food simulant C; and 2. food simulant B.]

Textual Amendments

F27 Substituted 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 \(Text with EEA relevance\).](#)

[^{F205} General derogation to the assignment of food simulants

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

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

ANNEX IV

Declaration of compliance

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

Status: Point in time view as at 31/12/2020.

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

- (1) the identity and address of the business operator issuing the declaration of compliance;
- (2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
- (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- (4) the date of the declaration;
- (5) [^{F2}confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;]
- (6) [^{F12}adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,
 - that are subject to restrictions in Annex II, or
 - for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;]
- (7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the ^{F28}... provisions applicable to food;
- (8) specifications on the use of the material or article, such as:
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) [^{F27}the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;]
- (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

Textual Amendments

F28 Words in Annex 4 para. 7 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, 77; 2020 c. 1, Sch. 5 para. 1(1)

Status: Point in time view as at 31/12/2020.

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

ANNEX V

COMPLIANCE TESTING

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

CHAPTER 1

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

1.1. Sample preparation

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

1.2. Conditions of testing

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

1.3. Analysis of migrated substances

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

[^{F2}1.4. **Account of substances originating from other sources**

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

CHAPTER 2

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

2.1. Verification method

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

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

2.1.1. Sample preparation

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

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

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

2.1.2. Choice of food simulant

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

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

2.1.3. Conditions of contact when using food simulants

[^{F2}The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

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

- (i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;
- (ii) if the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.
- (iv) [^{F26}if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:
 - the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and
 - the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of

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the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

The testing of the parts used for storage or supply such as reservoirs, containers, capsules or pads shall be under conditions representative of their use, and shall include the foreseeable storage conditions of the food in these parts.

The supporting documentation referred to in Article 16 shall clearly document the testing on the whole food processing and/or food producing equipment or appliance, or on parts thereof. It shall demonstrate that the testing was representative of its foreseeable use, and shall indicate for which substances migration testing was carried out and provide all testing results. The manufacturer of individual plastic parts shall ensure the absence of migration for substances for which the Regulation specifies that their migration shall not be detectable at a specified level of detection in accordance with Article 11(4).

Compliance documentation supplied in accordance with the Regulation to the producer of the final equipment or appliance, or part thereof, shall list all substances subject to migration limits that might be exceeded under the foreseeable use of the supplied part or material.

When the result is not in compliance with the Regulation it shall be determined whether the source of the non-compliance is a plastic part subject to the Regulation or a part made from another material not subject to the Regulation on the basis of documentary evidence or analytical testing. Without prejudice to Article 3 of Regulation (EU) No 1935/2004, non-compliance to the Regulation shall only be established if the migration originates from a plastic part.]

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

TABLE 1

[^{F2}Selection of test time]

Contact time in worst foreseeable use	[^{F2}Time to be selected for testing]
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours

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1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

^{F2}TABLE 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C ^a
121 °C < T ≤ 130 °C	130 °C ^a
130 °C < T ≤ 150 °C	150 °C ^a
150 °C < T < 175 °C	175 °C ^a
175 °C < T ≤ 200 °C	200 °C ^a
T > 200 °C	225 °C ^a

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

^{F2}2.1.4. *Specific conditions for contact times above 30 days at room temperature and below*

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C⁽²⁾.

- (a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum $t = 120/2^{((T-70)/10)}$ minutes.

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- (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.
- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

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

t1 is the contact time

t2 is the testing time

T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).

T2 is the testing temperature in Kelvin.]

2.1.5. Specific conditions for combinations of contact times and temperature

[^{F2}If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.]

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

[^{F12}2.1.6. *Repeated use materials and articles*

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. The specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

Compliance of the material or article shall then be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. The stability of the material shall be considered insufficient if migration is observed above the level of detection in any of the three migration tests, and increases from the first migration test to the third migration test. In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.

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

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in the first test a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected.]

2.1.7. Analysis of migrating substances

Status: Point in time view as at 31/12/2020.

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

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

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

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

2.2. Screening approaches

[^{F2}To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.]

2.2.1. Replacing specific migration by overall migration

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

2.2.2. Residual content

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

[^{F2}2.2.3. *Migration modelling*

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.]

[^{F2}2.2.4. *Food simulant substitutes*

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.]

[^{F20}2.2.5. *Single test for successive combinations of time and temperature*

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

Status: Point in time view as at 31/12/2020.

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

CHAPTER 3

Testing for overall migration

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

3.1. Standardised testing conditions

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

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

^{F12}TABLE 3

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing	Intended food contact conditions
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration (≤ 30 minutes).
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions
OM2	10 d at 40 °C	Any long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of $t = 120/2^{(T-70)/10}$ minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of $t = 120/2^{(T-70)/10}$ minutes, which are not followed by

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		long-term room temperature or refrigerated storage.
OM4	1 h at 100 °C or at reflux	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.]

[^{F2}3.2. Substitute overall migration tests for tests with food simulant D2

[^{F12}If it is not technically feasible to perform one or more of the tests OM0 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest overall migration shall be used to establish compliance with the Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2, either test OM8 or test OM9 shall be selected as a replacement test by selecting the most appropriate of these two tests on the basis of the intended and the foreseeable use of the material or article that is being tested. Subsequently, a migration test shall be done at each of the two test conditions specified for the selected test, using a new test sample for each test condition. The test condition that results in the higher overall migration shall be used to establish compliance with the Regulation.]

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5 and OM6
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6]

[^{F2}3.3. Verification of compliance

3.3.1. Single use articles and materials

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

[^{F12}3.3.2. Repeated use articles and materials

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council⁽⁹⁾. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to test the same sample three times, such as when testing in vegetable oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, the difference between the second and the first test results shall be lower than the first test results and the difference between the third and the second test results shall be lower than the difference between the second and the first test results.

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

3.4. Screening approaches

[^{F2}To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2.]

3.4.1. Residual content

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

[^{F2}3.4.2. Food simulant substitutes

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

To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.]

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

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

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

The FRF shall be applied according to the following rules.

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

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

- (a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;
- (b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

[^{F2}The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.]

[^{F20}When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.]

^{F3}4.2. Correction of migration into food simulant D2

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^{F3}4.3. Combination of correction factors 4.1 and 4.2.

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ANNEX VI

Correlation tables

Directive 2002/72/EC

This Regulation

Status: Point in time view as at 31/12/2020.

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

Article 1(1)	Article 1
Article 1(2), (3) and (4)	Article 2
Article 1a	Article 3
Article 3(1), Article 4(1) and Article 5	Article 5
Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3)	Article 6
Article 4a(3) and (6)	Article 7
Annex II (4) and Annex III (4)	Article 8
Article 3(1) and Article 4(1)	Article 9
Article 6	Article 10
Article 5a(1) and Annex I (8)	Article 11
Article 2	Article 12
Article 7a	Article 13
Article 9(1) and (2)	Article 15
Article 9(3)	Article 16
Article 7 and Annex I (5a)	Article 17
Article 8	Article 18
Annex II (3) and Annex III (3)	Article 19
Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI	Annex I
Annex II (2), Annex III (2) and Annex V, Part A	Annex II
Article 8(5) and Annex VIa	Annex IV
Annex I	Annex V
Directive 93/8/EEC	This Regulation
Article 1	Article 11
Article 1	Article 12
Article 1	Article 18
Annex	Annex III
Annex	Annex V
Directive 97/48/EC	This Regulation
Annex	Annex III
Annex	Annex V

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- (1) [^{F12}Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).:]
- (2) [^{F2}When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.]
- (3) [^{F2}[^{F12}Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).]]

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).
- 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).

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