

هيئة التقييس لدول مجلس التعاون دول الخليج العربية GCC STANDARDIZATION ORGANIZATION (GSO)

مشروع لائحة نهائي
Draft of Standard FDS

اعداد اللجنة الفنية الخليجية رقم TC05

Prepared by GSO Technical Committee No. TC05

GSO 1836 /2017

عبوات المواد الغذائية

الجزء الثاني: العبوات البلاستيكية – اشتراطات عامة

Food packages – Part 2: Plastic package - General requirements

I.C.S: 67.250

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هذه الوثيقة مشروع لمواصفة قياسية خليجية تم توزيعها لإبداء الرأي والملاحظات بشأنها، لذلك فإنها عرضة للتغيير والتبديل، ولا يجوز الرجوع إليها كمواصفة قياسية خليجية إلا بعد اعتمادها من الهيئة.

Foreword

GCC Standardization Organization (GSO) is a regional Organization which consists of the National Standards Bodies of GCC member States. One of GSO main functions is to issue Gulf Standards /Technical regulations through specialized technical committees (TCs).

GSO through the technical program of committee TC No (5) " Technical committee for standards of food and agriculture products " has prepared this Standard. The Draft Standard has been prepared by Kingdom of Saudi Arabia .

This standard has been approved as Gulf (Technical Regulation) by GSO Board of Directors in its meeting No. (), held on / / H , / / G. The approved standard will replace and supersede the GSO standard No.

Food packages - part 2: plastic packages – General requirements

1. Scope:

This standard is concerned with the general requirements of plastic packages in contact with food.

2. Complementary references:

- 2.1 GSO 839 “Food Packages - Part 1: General Requirements”.
- 2.2 GSO to be approved by GCC Standardization Organization on “Food Packages - Methods of Testing of Plastic Packages”.
- 2.3 GSO to be approved by GCC Standardization Organization on Recycled Plastic Materials and Articles Intended to Come into Contact with Foods.

3. Definitions:

3.1 Plastic materials: materials manufactured from simple petrochemical products of low molecular weights by polymerization to produce high molecular weight compounds such as polyethylene, polypropylene, polyvinyl chloride, polystyrene, and polyethylene terephthalate.

3.2 Plastic packaging materials: plastic materials (item 3.1) which soften when exposed to heat. Those materials are manufactured and formed using specific methods such as extrusion, injection blow molding, stretch blow molding, thermoforming, tube extrusion, rotational molding, compression molding, or any other new methods. Some materials such as colourants, stabilizers, antioxidants, and plasticizers, may be added during processing in order to attain specific properties to satisfy end application requirements. Plastic packaging materials include many types such as flexible films, soft, semi-rigid, and rigid materials.

3.3 Plastic package: a package made of a plastic material (item 3.2) to be used for packaging a food material for purposes of attaining containment, protection and preservation. Plastic packages come in many forms such as

bottles, bags, plates, trays, cups, flexible or rigid tubes, jars, pouches, barrels, boxes, woven sacks, or any other geometrical shapes.

3.4 Antioxidants: materials added to the plastic material to avoid its oxidation during processing, storage, and final use.

3.5 Permeability of gases and water vapors: a measure of the rate of permeable of the gasor vapour through a specific thickness of the plastic material at specific conditions of temperature, pressure and relative humidity.

3.6 Creep: a measure of deformation that takes place with time when the plastic material is exposed to a constant load.

3.7 Degradation of the plastic package: occurrence of a sensible change in its chemical composition, physical properties and appearance.

3.8 Dimensional stability: ability of the package to retain its initial dimensions and shape.

3.9 The overall migration limit means the amount of non-volatile substances released from a material or article into food simulants;

3.10 The specific migration is the amount of a specific substance in food.

3.11 The food simulant means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;

4. General Requirements:

Without violation of packaging requirements stated in GSO standard mentioned in item (2.1), the following general requirements for plastic packages used in packaging food materials shall be met:

4.1 All plastic raw materials used in manufacturing food packages shall be of known origin and composition.

4.2 They shall be clean and homogeneous, free from any foreign materials, swelling or air pockets.

4.3 They shall not cause any hazards to consumer health.

4.4 They shall not lead to degradation of sensory properties of the packaged food material, or occurrence of undesirable changes in the nature and quality of food material.

4.5 Pigments, colouring materials, and other components used in their formulation and manufacture shall be nonpoisonous and with no tendency for migration which may cause migrated components to react or mix with the food material.

4.6 They shall be resistant to impact effects caused by shocks and mechanical vibrations.

4.7 When rigid and semi-rigid packages are dropped when empty for three consecutive times on a solid surface from a 75 cm height, they shall not crack, tear, or lose any intactness.

4.8 They shall not be affected by heat during filling, closing, storing, transportation, or handling, in a way that deform them or change their composition, chemical or physical properties; or increase probabilities of reactions and migrations of monomers or additive materials within the permissible levels.

4.9 Their creep value shall be low in order to avoid problems arising as a result of stacking and handling and they shall be characterized with good dimensional stability in order to avoid printing difficulties.

4.10 Their resistance to acids and bases shall be suitable to the packaged food material.

4.11 The pH of a water solution within the range of 6-8 shall not be changed when placed in the package for one hour.

4.12 They shall be nonreactable with organic solvents and oils in packaged food materials.

4.13 Their permeability to water vapour shall be suitable to the packaged food material.

4.14 Their permeability to gases shall be suitable to the packaged food material.

4.15 They shall not be affected by light when exposed to it for long periods.

4.16 They shall have the ability of attaining tight closure (or sealing) when hermetic sealing used as a sterilizable package for food materials.

4.17 The concentration of vinyl chloride monomer shall not exceed 1 mg per kg of the plastic material, or 0.01 mg per kg of the packaged food material, in the case of packages made of polyvinyl chloride (PVC).

4.18 The concentration of the monomer of styrene in the plastic material shall not exceed 1% by weight in packages of non-fatty food materials, and shall not exceed 0.5% in packages of fatty food materials, in the case of packages made of polystyrene or modified rubbery polystyrene.

4.19 The concentration of acrylonitrile monomer shall not exceed 0.005 mg per kg of the plastic material or 0.02 mg per kg of the food material, in the case of packages made of acrylonitrile.

4.20 In the case of manufacturing multilayered packages from more than one material, it shall be necessary to get rid of the remaining of solvents, gluing materials, or major materials, such that the remains of all those solvents together shall not exceed 5 mg per square meter of the package surface.

4.21 Overall migration less than 10 mg/dm² or 60 mg/kg.

4.22* All released primary aromatic amines shall not be detected with a detection limit of 10 µg/kg.

4.22 In case scrap or perused raw materials are used in manufacturing food packages materials they should be in accordance with 2.3.

5. Materials:

5.1 list of authorized 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 EU 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 authorized to be used as additive or polymer production aid (yes) or if the substance is not authorized to be used as additive or polymer production aid (no). If the substance is only authorized 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 authorized to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorized to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (no). If

the substance is authorized as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

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

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

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

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

If in Column 8 the specific migration limit is non-detectable (ND) a detection limit of 0.01 mg substance per kg food is applicable unless specified differently for an individual substance.

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 production aid (yes/no)	Use as mono- mer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-12-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₂₂)	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C ₅ -C ₁₅)acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 42 Da	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		
9	30610	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	yes	no	no				

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10	30612	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no					
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	11	30960	—	acids, aliphatic, monocarboxylic 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 -C ₁₃) benzenesulphonic acid	yes	no	no	30			
	15	34130	—	alkyl, linear with even number of carbon atoms (C ₁₂ -C ₂₀) dimethylamines	yes	no	yes	30			
	16	34230	—	alkyl(C ₈ -C ₂₂)sulphonic acids	yes	no	no	6			
	17	34281	—	alkyl(C ₈ -C ₂₂)sulphuric acids, linear, primary with an even number of carbon atoms	yes	no	no				
	18	34475	—	aluminium calcium hydroxide phosphite, hydrate	yes	no	no				
	19	39090	—	N,N-bis(2-hydroxyethyl)alkyl (C ₈ -C ₁₈)amine	yes	no	no	(7)			
	20	39120	—	N,N-bis(2-hydroxyethyl)alkyl	yes	no	no	(7) SML(T) expressed excluding			

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(C ₈ -C ₁₈)amine hydrochlorides							HCl			
21	42500	—	carbonic acid, salts	yes	no	no				
22	43200	—	castor oil, mono- and diglycerides	yes	no	no				
23	43515	—	chlorides of choline esters of coconut oil fatty acids	yes	no	no	0,9			(1)
24	45280	—	cotton fibers	yes	no	no				
25	45440	—	cresols, butylated, styrenated	yes	no	no	12			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	yes	no	no	5			
27	48960	—	9,10-dihydroxy stearic acid and its oligomers	yes	no	no	5			
28	50160	—	di-n-octyltin bis(n-alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	yes	no	no			(10)	
29	50360	—	di-n-octyltin bis(ethyl maleate)	yes	no	no			(10)	
30	50560	—	di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	yes	no	no			(10)	
31	50800	—	di-n-octyltin dimaleate,	yes	no	no			(10)	

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esterified										
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	—	ethylhydroxymethylcellulose	yes	no	no				
35	54280	—	ethylhydroxypropylcellulose	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and oils, hydrogenated, from animal or vegetable food sources	yes	no	no				
38	55520	—	glass fibers	yes	no	no				
39	55600	—	glass microballs	yes	no	no				
40	56360	—	glycerol, esters with acetic acid	yes	no	no				
		(1)		(2)	(3)	(4)	(5)	(6)	(7)	(8) (9) (10) (11)
	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		

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42	56487	—	glycerol, esters with butyric acid	yes	no	no
43	56490	—	glycerol, esters with erucic acid	yes	no	no
44	56495	—	glycerol, esters with 12-hydroxystearic acid	yes	no	no
45	56500	—	glycerol, esters with lauric acid	yes	no	no
46	56510	—	glycerol, esters with linoleic acid	yes	no	no
47	56520	—	glycerol, esters with myristic acid	yes	no	no
48	56535	—	glycerol, esters with nonanoic acid	yes	no	no
49	56540	—	glycerol, esters with oleic acid	yes	no	no
50	56550	—	glycerol, esters with palmitic acid	yes	no	no
51	56570	—	glycerol, esters with propionic acid	yes	no	no
52	56580	—	glycerol, esters with ricinoleic acid	yes	no	no
53	56585	—	glycerol, esters with stearic acid	yes	no	no
54	57040	—	glycerol monooleate, ester with ascorbic acid	yes	no	no

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55				57120	—	glycerol monooleate, ester with citric acid		yes	no	no
56				57200	—	glycerol monopalmitate, ester with ascorbic acid		yes	no	no
57				57280	—	glycerol monopalmitate, ester with citric acid		yes	no	no
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
58	57600	—	glycerol monostearate, ester with ascorbic acid	yes	no	no				
59	57680	—	glycerol monostearate, ester with citric acid	yes	no	no				
60	58300	—	glycine, salts	yes	no	no				
62	64500	—	lysine, salts	yes	no	no				
63	65440	—	manganese pyrophosphite	yes	no	no				
64	66695	—	methylhydroxymethylcellulose	yes	no	no				
65	67155	—	mixture of 4-(2-benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl) stilbene, 4,4'-bis (2-benzoxazolyl) stilbene and	yes	no	no				Not more than 0,05 % (w/w) (quantity of substance used/quantity of the formulation).

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			4,4'-bis(5-methyl-2-benzoxazolyl)stilbene					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 and/or with glycerol	yes	no	no		
68	73160	—	phosphoric acid, mono- and di-n-alkyl (C ₁₆ and C ₁₈) esters	yes	no	yes	0,05	
69	74400	—	phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	yes	no	yes	30	
70	76463	—	polyacrylic acid, salts	yes	no	no	(22)	
71	76730	—	polydimethylsiloxane, γ -hydroxypropylated	yes	no	no	6	
72	76815	—	polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered,		no	no	(32)	The fraction with molecular weight below 1 000 Da should not exceed 5 %

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			unbranched C ₁₂ - C ₂₂ fatty acids					(w/w)		
73	76866	—	polyesters of 1,2- propanediol and/or 1,3- and/or 1,4- butanediol and/or polypropylene- glycol with adipic acid, which may be end- capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n- octanol and/or n- decanol	yes	no	yes			(31)	
									(32)	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
74	77440	—	polyethyleneglycol yes dicinoleate		no	yes	42			
75	77702	—	polyethyleneglycol yes esters of aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates		no	no				
76	77732	—	polyethylene glycol yes (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4- hydroxy- 3-methoxyphenyl) acrylate		no	no	0,05		Only for use in PET	

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77	77733	—	polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	yes	no	no	0,05	Only for use in PET
78	77897	—	polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C ₈ -C ₂₀) sulphate, salts	yes	no	no	5	
79	80640	—	polyoxyalkyl (C ₂ -C ₄) dimethylpolysiloxane	yes	no	no		
80	81760	—	powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	yes	no	no		
81	83320	—	propylhydroxyethylcellulose	yes	no	no		
82	83325	—	propylhydroxymethylcellulose	yes	no	no		
83	83330	—	propylhydroxypropylcellulose	yes	no	no		
84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no		

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85	85610	—	silicates, natural, silanated (with the exception of asbestos)	yes	no	no				
86	86000	—	silicic acid, silylated	yes	no	no				
87	86285	—	silicon dioxide, silanated	yes	no	no				
88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no	(2)		(2)	
90	92195	—	taurine, salts	yes	no	no				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
91	92320	--	tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	yes	no	yes	15			
92	93970	—	Tricyclodecanedimethanol bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down.	

Average molecular weight

not less than 350 Da.

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

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carbons with Carbon num-

ber less than 25, not more

than 5 % (w/w).

96	95920	—	wood flour and fibers, untreated	yes	no	no				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
97	72081/10	—	petroleum hydrocarbon resins (hydrogenated)	yes	no	no	Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of ienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: - Viscosity at 120 °C:> 3 Pa.s, - Softening point:> 95 °C as determined by ASTM Method E 28-67, - Bromine number: < 40 (ASTM D1159), - The colour of a 50% solution in toluene < 11 on the Gardner scale, - Residual aromatic monomer ≤ 50 ppm,			
98	17260 54880	0000050-00-0	formaldehyde	yes	yes	no	(15)			
99	19460 62960	0000050-21-5	lactic acid	yes	yes	no				
100	24490 88320	0000050-70-4	sorbitol	yes	yes	no				
101	36000	0000050-81-7	ascorbic acid	yes	no	no				
102	17530	0000050-99-7	glucose	no	yes	no				
103	18100 55920	0000056-81-5	glycerol	yes	yes	no				

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
104	58960	0000057-09-0	hexadecyltrimethylammonium bromide	yes	no	no	6			
105	22780	0000057-10-3	palmitic acid	yes	yes	no				
	70400									
106	24550	0000057-11-4	stearic acid	yes	yes	no				
	89040									
107	25960	0000057-13-6	urea	no	yes	no				
108	24880	0000057-50-1	sucrose	no	yes	no				
109	23740	0000057-55-6	1,2-propanediol	yes	yes	no				
	81840									
110	93520	0000059-02-9	α -tocopherol	yes	no	no				
		0010191-41-0								
111	53600	0000060-00-4	ethylenediaminetetraacetic acid	yes	no	no				
112	64015	0000060-33-3	linoleic acid	yes	no	no				
113	16780	0000064-17-5	ethanol	yes	yes	no				
	52800									
114	55040	0000064-18-6	formic acid	yes	no	no				
115	10090	0000064-19-7	acetic acid	yes	yes	no				
	30000									

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116	13090	0000065-85-0	benzoic acid	yes	yes	no				
	37600									
117	21550	0000067-56-1	methanol	no	yes	no				
118	23830	0000067-63-0	2-propanol	yes	yes	no				
	81882									
119	30295	0000067-64-1	acetone	yes	no	no				
120	49540	0000067-68-5	dimethyl sulphoxide	yes	no	no				
121	24270	0000069-72-7	salicylic acid	yes	yes	no				
	84640									
122	23800	0000071-23-8	1-propanol	no	yes	no				
123	13840	0000071-36-3	1-butanol	no	yes	no				
124	22870	0000071-41-0	1-pentanol	no	yes	no				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
125	16950	0000074-85-1	ethylene	no	yes	no				
126	10210	0000074-86-2	acetylene	no	yes	no				
127	26050	0000075-01-4	vinyl chloride	no	yes	no	ND	1 mg/kg in final product		
128	10060	0000075-07-0	acetaldehyde	no	yes	no		(1)		

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129	17020 0000075-21-8	ethylene oxide	no	yes	no	ND	1 mg/kg in final product	(10)
130	26110 0000075-35-4	vinylidene chloride	no	yes	no	ND		(1)
131	48460 0000075-37-6	1,1-difluoroethane	yes	no	no			
132	26140 0000075-38-7	vinylidene fluoride	no	yes	no	5		
133	14380 0000075-44-5	carbonyl chloride	no	yes	no	ND	1 mg/kg in final product	(10)
	23155							
134	43680 0000075-45-6	chlorodifluoromethane	yes	no	no	6	Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010 0000075-56-9	propylene oxide	no	yes	no	ND	1 mg/kg in final product	
136	41680 0000076-22-2	camphor	yes	no	no			(3)
137	66580 0000077-62-3	2,2'-methylenebis(4-methyl-6- (1-methylcyclohexyl)phenol)	yes	no	yes		(5)	
138	93760 0000077-90-7	tri-n-butyl acetyl citrate	yes	no	no		(32)	
139	14680 0000077-92-9	citric acid	yes	yes	no			
	44160							
140	44640 0000077-93-0	citric acid, triethyl ester	yes	no	no		(32)	
141	13380 0000077-99-6	1,1,1-trimethylolpropane	yes	yes	no	6		
	25600							
	94960							
142	26305 0000078-08-0	vinyltriethoxysilane	no	yes	no	0,05	Only to be used as a surface treatment agent	(1)

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143	62450 0000078-78-4	isopentane	yes	no	no				
144	19243 0000078-79-5	2-methyl-1,3-butadiene	no	yes	no	ND	1 mg/kg in final product		
	21640								
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
145	10630 0000079-06-1	acrylamide	no	yes	no	ND			
146	23890 0000079-09-4	propionic acid	yes	yes	no				
	82000								
147	10690 0000079-10-7	acrylic acid	no	yes	no		(22)		
148	14650 0000079-38-9	chlorotrifluoroethylene	no	yes	no	ND			(1)
149	19990 0000079-39-0	methacrylamide	no	yes	no	ND			
150	20020 0000079-41-4	methacrylic acid	no	yes	no		(23)		
151	13480 0000080-05-7	2,2-bis(4-hydroxyphenyl) propane	no	yes	no	0,6		Not to be used for the manufacture polycarbonate infant feeding botles	
	13607								
152	15610 0000080-07-9	4,4'-dichlorodiphenyl sulphone	no	yes	no	0,05			
153	15267 0000080-08-0	4,4'-diaminodiphenyl sulphone	no	yes	no	5			
154	13617 0000080-09-1	4,4'-dihydroxydiphenyl sulphone	no	yes	no	0,05			
	16090								

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155	23470 0000080-56-8	α -pinene	no	yes	no						
156	21130 0000080-62-6	methacrylic acid, methyl ester	no	yes	no		(23)				
157	74880 0000084-74-2	phthalic acid, dibutyl ester	yes	no	no	0,3	(32) Only to be used as:			(7)	
							(a) plasticizer in reported use materials and articles contacting non-fatty foods;				
							(b) technical support agent in polyolefins in contrations up to 0.05% in the final				
158	23380 0000085-44-9	Phthatic anhydride	yes	yes	no						
	76320										
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	
159	74560 0000085-68-7	phthalic acid, benzyl butyl ester		yes	no	no	30	(32) Only to be used as:		(7)	
								(a) plasticiser in repeated use materials and articles;			
								(b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or pro- cessed 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 to 0,1 % in the final product.			
160	84800 0000087-18-3	salicylic acid, 4-tert-butylphenyl ester		yes	no	yes	12				
161	92160 0000087-69-4	tartaric acid		yes	no	no					
162	65520 0000087-78-5	mannitol		yes	no	no					
163	66400 0000088-24-4	2,2'-methylene bis(4-ethyl-6- tert-butylphenol)		yes	no	yes		(13)			
164	34895 0000088-68-6	2-aminobenzamide		yes	no	no	0,05				

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165	23200	0000088-99-3	o-phthalic acid			yes	yes	no		
		74480								
166	24057	0000089-32-7	pyromellitic anhydride			no	yes	no	0,05	
167	25240	0000091-08-7	2,6-toluene diisocyanate			no	yes	no	(17)	
168	13075	0000091-76-9	2,4-diamino-6-phenyl-1,3,5- triazine			no	yes	no	5	
		15310								
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
169	16240	0000091-97-4	3,3'-dimethyl-4,4'-diisocyanatobiphenyl	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
170	16000	0000092-88-6	4,4'-dihydroxybiphenyl	no	yes	no	6			
171	38080	0000093-58-3	benzoic acid, methyl ester	yes	no	no				
172	37840	0000093-89-0	benzoic acid, ethyl ester	yes	no	no				
173	60240	0000094-13-3	4-hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	0000095-48-7	o-cresol	no	yes	no				
175	20050	0000096-05-9	methacrylic acid, allyl ester	no	yes	no	0,05			
176	11710	0000096-33-3	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	0000096-49-1	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneg-lycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	

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178	92800	0000096-69-5	4,4'-thiobis(6-tert-butyl-3-methylphenol)	yes	no	yes	0,48
179	48800	0000097-23-4	2,2'-dihydroxy--5,5'-dichlorodiphenylmethane	yes	no	yes	12
180	17160	0000097-53-0	eugenol	no	yes	no	ND
181	20890	0000097-63-2	methacrylic acid, ethyl ester	no	yes	no	(23)
182	19270	0000097-65-4	itaconic acid	no	yes	no	
183	21010	0000097-86-9	methacrylic acid, isobutyl ester	no	yes	no	(23)
184	20110	0000097-88-1	methacrylic acid, butyl ester	no	yes	no	(23)
185	20440	0000097-90-5	methacrylic acid, diester with ethyleneglycol	no	yes	no	0,05
186	14020	0000098-54-4	4-tert-butylphenol	no	yes	no	0,05
187	22210	0000098-83-9	α -methylstyrene	no	yes	no	0,05
188	19180	0000099-63-8	isophthalic acid dichloride	no	yes	no	(27)
189	60200	0000099-76-3	4-hydroxybenzoic acid, methyl ester	yes	no	no	
190	18880	0000099-96-7	<i>p</i> -hydroxybenzoic acid	no	yes	no	
191	24940	0000100-20-9	terephthalic acid dichloride	no	yes	no	(28)
192	23187	—	phthalic acid	no	yes	no	(28)
193	24610	0000100-42-5	styrene	no	yes	no	

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
194	13150	0000100-51-6	benzyl alcohol	no	yes	no				
195	37360	0000100-52-7	benzaldehyde	yes	no	no				(3)
196	18670	0000100-97-0	hexamethylenetetramine	yes	yes	no		(15)		
	59280									
197	20260	0000101-43-9	methacrylic acid, cyclohexyl ester	no	yes	no	0,05			
198	16630	0000101-68-8	diphenylmethane-4,4'-diisocyanate	no	yes	no		(17) 1 mg/kg in final product expressed as isocyanate moiety		(10)
199	24073	0000101-90-6	resorcinol diglycidyl ether	no	yes	no	ND	Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.		(8)
200	51680	0000102-08-9	N,N'-diphenylthiourea	yes	no	yes	3			
201	16540	0000102-09-0	diphenyl carbonate	no	yes	no	0,05			
202	23070	0000102-39-6	(1,3-phenylenedioxy) diacetic acid	no	yes	no	0,05			(1)
203	13323	0000102-40-9	1,3-bis(2-hydroxyethoxy) benzene	no	yes	no	0,05			
204	25180	0000102-60-3	N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
	92640									
205	25385	0000102-70-5	triallylamine	no	yes	no		40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. Only to be used in hydro- gels intended for non-direct food contact use.		
206	11500	0000103-11-7	acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05			

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207	31920	0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)				(2)
208	18898	0000103-90-2	N-(4-hydroxyphenyl) acetamide	no	yes	no	0,05					
209	17050	0000104-76-7	2-ethyl-1-hexanol	no	yes	no	30					
210	13390 14880	0000105-08-8	1,4-bis(hydroxymethyl)	no	yes	no						
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	211	23920	0000105-38-4	propionic acid, vinyl ester	no	yes	no			(1)		
	212	14200	0000105-60-2	caprolactam	yes	yes	no			(4)		
		41840										
	213	82400	0000105-62-4	1,2-propyleneglycol dioleate	yes	no	no					
	214	61840	0000106-14-9	12-hydroxystearic acid	yes	no	no					
	215	14170	0000106-31-0	butyric anhydride	no	yes	no					
	216	14770	0000106-44-5	p-cresol	no	yes	no					
	217	15565	0000106-46-7	1,4-dichlorobenzene	no	yes	no	12				
	218	11590	0000106-63-8	acrylic acid, isobutyl ester	no	yes	no			(22)		
	219	14570	0000106-89-8	epichlorohydrin	no	yes	no	ND		1 mg/kg in final product		(10)
		16750										
	220	20590	0000106-91-2	methacrylic acid, 2,3-epoxypropyl ester	no	yes	no	0,02				(10)
	221	40570	0000106-97-8	butane	yes	no	no					

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222	13870	0000106-98-9	1-butene	no	yes	no		
223	13630	0000106-99-0	butadiene	no	yes	no	ND	1 mg/kg in final product
224	13900	0000107-01-7	2-butene	no	yes	no		
225	12100	0000107-13-1	acrylonitrile	no	yes	no	ND	
226	15272	0000107-15-3	ethylenediamine	no	yes	no	12	
	16960							
227	16990	0000107-21-1	ethyleneglycol	yes	yes	no	(2)	
	53650							
228	13690	0000107-88-0	1,3-butanediol	no	yes	no		
229	14140	0000107-92-6	butyric acid	no	yes	no		
230	16150	0000108-01-0	dimethylaminoethanol	no	yes	no	18	
231	10120	0000108-05-4	acetic acid, vinyl ester	no	yes	no	12	
232	10150	0000108-24-7	acetic anhydride	yes	yes	no		
	30280							
233	24850	0000108-30-5	succinic anhydride	no	yes	no		
234	19960	0000108-31-6	maleic anhydride	no	yes	no	(3)	
235	14710	0000108-39-4	m-cresol	no	yes	no		

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
236	23050	0000108-45-2	1,3-phenylenediamine	no	yes	no	ND			
237	15910	0000108-46-3	1,3-dihydroxybenzene	no	yes	no	2,4			
	24072									
238	18070	0000108-55-4	glutaric anhydride	no	yes	no				
239	19975	0000108-78-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	30			
	25420									
	93720									
240	45760	0000108-91-8	cyclohexylamine	yes	no	no				
241	22960	0000108-95-2	phenol	no	yes	no				
242	85360	0000109-43-3	sebacic acid, dibutyl ester	yes	no	no		(32)		
243	19060	0000109-53-5	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	0000109-66-0	pentane	yes	no	no				
245	22900	0000109-67-1	1-pentene	no	yes	no	5			
246	25150	0000109-99-9	tetrahydrofuran	no	yes	no	0,6			
247	24820	0000110-15-6	succinic acid	yes	yes	no				
	90960									
248	19540	0000110-16-7	maleic acid	yes	yes	no		(3)		
	64800									
249	17290	0000110-17-8	fumaric acid	yes	yes	no				
	55120									
250	53520	0000110-30-5	N,N'-ethylenebisstearamide	yes	no	no				
251	53360	0000110-31-6	N,N'-ethylenebisoleamide	yes	no	no				

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252	87200	0000110-44-1	sorbic acid	yes	no	no				
253	15250	0000110-60-1	1,4-diaminobutane	no	yes	no				
254	13720	0000110-63-4	1,4-butanediol	yes	yes	no			(30)	
	40580									
255	25900	0000110-88-3	trioxane	no	yes	no			5	
256	18010	0000110-94-1	glutaric acid	yes	yes	no				
	55680									
257	13550	0000110-98-5	dipropyleneglycol	yes	yes	no				
	16660									
	51760									
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
258	70480	0000111-06-8	palmitic acid, butyl ester	yes	no	no				
259	58720	0000111-14-8	heptanoic acid	yes	no	no				
260	24280	0000111-20-6	sebacic acid	no	yes	no				
261	15790	0000111-40-0	diethylenetriamine	no	yes	no	5			
262	35284	0000111-41-1	N-(2-aminoethyl)ethanolamine	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	
263	13326	0000111-46-6	diethyleneglycol	yes	yes	no		(2)		
	15760									
	47680									
264	22660	0000111-66-0	1-octene	no	yes	no	15			

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265	22600	0000111-87-5	1-octanol	no	yes	no					
266	<u>25510</u>	0000112-27-6	triethyleneglycol	yes	yes	no					
	94320										
267	15100	0000112-30-1	1-decanol	no	yes	no					
268	16704	0000112-41-4	1-dodecene	no	yes	no	0,05				
269	<u>25090</u>	0000112-60-7	tetraethyleneglycol	yes	yes	no					
	92350										
270	<u>22763</u>	0000112-80-1	oleic acid	yes	yes	no					
	69040										
271	52720	0000112-84-5	erucamide	yes	no	no					
272	37040	0000112-85-6	behenic acid	yes	no	no					
273	52730	0000112-86-7	erucic acid	yes	no	no					
274	22570	0000112-96-9	octadecyl isocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety			(10)
275	23980	0000115-07-1	propylene	no	yes	no					
276	19000	0000115-11-7	isobutene	no	yes	no					
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	
277	18280	0000115-27-5	hexachloroendomethylenetetra-hydrophthalic anhydride	no	yes	no	ND				

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278	18250 0000115-28-6	hexachloroendomethylenetetra-hydrophthalic acid	no	yes	no	ND		
279	22840 0000115-77-5 71600	pentaerythritol	yes	yes	no			
280	73720 0000115-96-8	phosphoric acid, trichloroethyl ester	yes	no	no	ND		
281	25120 0000116-14-3	tetrafluoroethylene	no	yes	no	0,05		
282	18430 0000116-15-4	hexafluoropropylene	no	yes	no	ND		
283	74640 0000117-81-7	phthalic acid, bis(2-ethylhexyl) ester	yes	no	no	1,5	(32) Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product.	(7)
284	84880 0000119-36-8	salicylic acid, methyl ester	yes	no	no	30		
285	66480 0000119-47-1	2,2'-methylene bis(4-methyl-6- tert-butylphenol)	yes	no	yes		(13)	
286	38240 0000119-61-9	benzophenone	yes	no	yes	0,6		
287	60160 0000120-47-8	4-hydroxybenzoic acid, ethyl ester	yes	no	no			
288	24970 0000120-61-6	terephthalic acid, dimethyl ester	no	yes	no			
289	15880 0000120-80-9 24051	1,2-dihydroxybenzene	no	yes	no	6		
290	55360 0000121-79-9	gallic acid, propyl ester	yes	no	no		(20)	
291	19150 0000121-91-5	isophthalic acid	no	yes	no		(27)	
292	94560 0000122-20-3	triisopropanolamine	yes	no	no	5		
293	23175 0000122-52-1	phosphorous acid, triethyl ester	no	yes	no	ND	1 mg/kg in final product	(1)
294	93120 0000123-28-4	thiodipropionic acid, didodecyl ester	yes	no	yes		(14)	
295	15940 0000123-31-9 18867 48620	1,4-dihydroxybenzene	yes	yes	no	0,6		

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
296		23860	0000123-38-6	propionaldehyde	no	yes	no			
297		23950	0000123-62-6	propionic anhydride	no	yes	no			
298		14110	0000123-72-8	butyraldehyde	no	yes	no			
299		63840	0000123-76-2	levulinic acid	yes	no	no			
300		30045	0000123-86-4	acetic acid, butyl ester	yes	no	no			
301		89120	0000123-95-5	stearic acid, butyl ester	yes	no	no			
302		12820	0000123-99-9	azelaic acid	no	yes	no			
303		12130	0000124-04-9	adipic acid	yes	yes	no			
		31730								
304		14320	0000124-07-2	caprylic acid	yes	yes	no			
		41960								
305		15274	0000124-09-4	hexamethylenediamine	no	yes	no	2,4		
		18460								
306		88960	0000124-26-5	stearamide	yes	no	no			
307		42160	0000124-38-9	carbon dioxide	yes	no	no			
308		91200	0000126-13-6	sucrose acetate isobutyrate	yes	no	no			
309		91360	0000126-14-7	sucrose octaacetate	yes	no	no			
310		16390	0000126-30-7	2,2-dimethyl-1,3-propanediol	no	yes	no	0,05		
		22437								
311		16480	0000126-58-9	dipentaerythritol	yes	yes	no			

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51200										
312		21490	0000126-98-7	methacrylonitrile	no	yes	no	ND		
313		16650	0000127-63-9	diphenyl sulphone	yes	yes	no	3		
51570										
314		23500	0000127-91-3	β-pinene	no	yes	no			
315		46640	0000128-37-0	2,6-di-tert-butyl-p-cresol	yes	no	no	3		
316		23230	0000131-17-9	phthalic acid, diallyl ester	no	yes	no	ND		
317	(8)	48880	0000131-53-3	2,2'-dihydroxy-4-methoxybenzophenone	yes	no	yes			
318	(8)	48640	0000131-56-6	2,4-dihydroxybenzophenone	yes	no	no			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10) (11)
	319	61360	0000131-57-7	2-hydroxy-4-methoxybenzophenone	yes	no	yes		(8)	
	320	37680	0000136-60-7	benzoic acid, butyl ester	yes	no	no			
	321	36080	0000137-66-6	ascorbyl palmitate	yes	no	no			
	322	63040	0000138-22-7	lactic acid, butyl ester	yes	no	no			
	323	11470	0000140-88-5	acrylic acid, ethyl ester	no	yes	no		(22)	
	324	83700	0000141-22-0	ricinoleic acid	yes	no	yes	42		
	325	10780	0000141-32-2	acrylic acid, n-butyl ester	no	yes	no		(22)	
	326	12763	0000141-43-5	2-aminoethanol	yes	yes	no	0,05	Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	
35170										
	327	30140	0000141-78-6	acetic acid, ethyl ester	yes	no	no			
	328	65040	0000141-82-2	malonic acid	yes	no	no			

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329	59360	0000142-62-1 hexanoic acid	yes	no	no
330	19470	0000143-07-7 lauric acid	yes	yes	no
	63280				
331	22480	0000143-08-8 1-nonanol	no	yes	no
332	69760	0000143-28-2 oleyl alcohol	yes	no	no
333	22775	0000144-62-7 oxalic acid	yes	yes	no 6
	69920				
334	17005	0000151-56-4 ethyleneimine	no	yes	no ND
335	68960	0000301-02-0 oleamide	yes	no	no
336	15095	0000334-48-5 n-decanoic acid	yes	yes	no
	45940				
337	15820	0000345-92-6 4,4'-difluorobenzophenone	no	yes	no 0,05
338	71020	0000373-49-9 palmitoleic acid	yes	no	no
339	86160	0000409-21-2 silicon carbide	yes	no	no

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
340	47440	0000461-58-5	dicyanodiamide	yes	no	no				
341	<u>13180</u>	0000498-66-8	bicyclo[2.2.1]hept-2-ene	no	yes	no	0,05			
	22550									
342	14260	0000502-44-3	caprolactone	no	yes	no		(29)		
343	23770	0000504-63-2	1,3-propanediol	no	yes	no	0,05			
344	<u>13810</u>	0000505-65-7	1,4-butanediol formal	no	yes	no	ND			(10)
	21821									
345	35840	0000506-30-9	arachidic acid	yes	no	no				
346	10030	0000514-10-3	abietic acid	no	yes	no				
347	<u>13050</u>	0000528-44-9	trimellitic acid	no	yes	no		(21)		
	25540									
348	<u>22350</u>	0000544-63-8	myristic acid	yes	yes	no				

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349	25550	0000552-30-7	trimellitic anhydride	no	yes	no	(21)		
350	63920	0000557-59-5	lignoceric acid	yes	no	no			
351	21730	0000563-45-1	3-methyl-1-butene	no	yes	no	ND	Only to be used in polypropylene	(1)
352	16360	0000576-26-1	2,6-dimethylphenol	no	yes	no	0,05		
353	42480	0000584-09-8	carbonic acid, rubidium salt	yes	no	no	12		
354	25210	0000584-84-9	2,4-toluene diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
355	20170	0000585-07-9	methacrylic acid, tert-butyl ester	no	yes	no	(23)		
356	18820	0000592-41-6	1-hexene	no	yes	no	3		
357	13932	0000598-32-3	3-buten-2-ol	no	yes	no	ND	Only to be used as a co-monomer for the preparation of polymeric additive	(1)
358	14841	0000599-64-4	4-cumylphenol	no	yes	no	0,05		
359	<u>15970</u> 48720	0000611-99-4	4,4'-dihydroxybenzophenone	yes	yes	no	(8)		
360	57920	0000620-67-7	glycerol triheptanoate	yes	no	no			
361	18700	0000629-11-8	1,6-hexanediol	no	yes	no	0,05		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(11)
362	14350	0000630-08-0	carbon monoxide	no	yes	no			
363	16450	0000646-06-0	1,3-dioxolane	no	yes	no	5		
364	15404	0000652-67-5	1,4:3,6-dianhydrosorbitol	no	yes	no	5	Only to be used as a co-monomer in poly(ethylene-co-isosorbide terephthalate)	
365	11680	0000689-12-3	acrylic acid, isopropyl ester	no	yes	No	(22)		

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366	22150	0000691-37-2	4-methyl-1-pentene	no	yes	no	0,05			
367	16697	0000693-23-2	n-dodecanedioic acid	no	yes	no				
368	93280	0000693-36-7	thiodipropionic acid, dioctadecyl ester	yes	no	yes	(14)			
369	12761	0000693-57-2	12-aminododecanoic acid	no	yes	no	0,05			
370	21460	0000760-93-0	methacrylic anhydride	no	yes	no	(23)			
371	11510 11830	0000818-61-1	acrylic acid, monoester with ethyleneglycol	no	yes	no	(22)			
372	18640	0000822-06-0	hexamethylene diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety		(10)
373	22390	0000840-65-3	2,6-naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	0000868-77-9	methacrylic acid, monoester with ethyleneglycol	no	yes	no	(23)			
375	15130	0000872-05-9	1-decene	no	yes	no	0,05			
376	66905	0000872-50-4	N-methylpyrrolidone	yes	no	no				
377	12786	0000919-30-2	3-aminopropyltriethoxysilane	no		no		Residual extractable content of 3- aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treat- ment of materials and articles.		
378	21970	0000923-02-4	N-methylolmethacrylamide	no		no				
379	21940	0000924-42-5	N-methylolacrylamide	no		no				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
380	11980	0000925-60-0	acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931-88-4	cyclooctene	no	yes	no	0,05		Only to be used in polymers contacting foods for which simulant A is laid down	
382	19490	0000947-04-6	laurolactam	no	yes	no	5			
383	72160	0000948-65-2	2-phenylindole	yes	no	yes	15			

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384	40000	0000991-84-4	2,4-bis(octylmercapto)-6- (4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30	
385	11530	0000999-61-1	acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05	SML 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	0001034-01-1	gallic acid, octyl ester	yes	no	no	(20)	
387	26155	0001072-63-5	1-vinylimidazole	no	yes	no	0,05	(1)
388	25080	0001120-36-1	1-tetradecene	no	yes	no	0,05	
389	22360	0001141-38-4	2,6-naphthalenedicarboxylic acid	no	yes	no	5	
390	55200	0001166-52-5	gallic acid, dodecyl ester	yes	no	no	(20)	
391	22932	0001187-93-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05	Only to be used in anti-stick coatings
392	72800	0001241-94-7	phosphoric acid, diphenyl 2-ethylhexyl ester	yes	no	yes	2,4	
393	37280	0001302-78-9	bentonite	yes	no	no		
394	41280	0001305-62-0	calcium hydroxide	yes	no	no		
395	41520	0001305-78-8	calcium oxide	yes	no	no		
396	64640	0001309-42-8	magnesium hydroxide	yes	no	no		
397	64720	0001309-48-4	magnesium oxide	yes	no	no		
398	35760	0001309-64-4	antimony trioxide	yes	no	no	0,04	SML expressed as antimony (6)
399	81600	0001310-58-3	potassium hydroxide	yes	no	no		
400	86720	0001310-73-2	sodium hydroxide	yes	no	no		

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
401	24475	0001313-82-2	sodium sulphide	no	yes	no				
402	96240	0001314-13-2	zinc oxide	yes	no	no				
403	96320	0001314-98-3	zinc sulphide	yes	no	no				
404	67200	0001317-33-5	molybdenum disulphide	yes	no	no				
405	16690	0001321-74-0	divinylbenzene	no	yes	no	ND		SML expressed as the sum of divinylbenzene and eth- ylvinylbenzene.	(1)
									It may contain up to 45 % (m/m) of ethylvinylbenzene.	
406	83300	0001323-39-3	1,2-propyleneglycol monostear-	yes	no	no				
407	87040	0001330-43-4	sodium tetraborate	yes	no	no		(16)		
408	82960	0001330-80-9	1,2-propyleneglycol monooleate	yes	no	no				
409	62240	0001332-37-2	iron oxide	yes	no	no				
410	62720	0001332-58-7	kaolin	yes	no	no				
411	42080	0001333-86-4	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 distribution of 300 nm – mm. Toluene extractables: maxi- mum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohex-ane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognized method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of car-bon black in the polymer: 2,5 % w/w.	
412	45200	0001335-23-5	copper iodide	yes	no	no		(6)		
413	35600	0001336-21-6	ammonium hydroxide	yes	no	no				

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
414	87600	0001338-39-2	sorbitan monolaurate	yes	no	no				
415	87840	0001338-41-6	sorbitan monostearate	yes	no	no				
416	87680	0001338-43-8	sorbitan monooleate	yes	no	no				
417	85680	0001343-98-2	silicic acid	yes	no	no				
418	34720	0001344-28-1	aluminium oxide	yes	no	no				
419	92150	0001401-55-4	tannic acids	yes	no	no			According to the JECFA specifications	
420	19210	0001459-93-4	isophthalic acid, dimethyl ester	no	yes	no	0,05			
421	13000	0001477-55-0	1,3-benzenedimethanamine	no	yes	no	0,05			
422	38515	0001533-45-5	4,4'-bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05			(2)
423	22937	0001623-05-8	Perfluoropropylperfluorovinyl ether	no	yes	no	0,05			
424	15070	0001647-16-1	1,9-decadiene	no	yes	no	0,05			
425	10840	0001663-39-4	acrylic acid, tert-butyl ester	no	yes	no		(22)		
426	<u>13510</u> 13610	0001675-54-3	2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005 ⁽¹⁾	
427	18896	0001679-51-2	4-(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	0001709-70-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene	yes	no	no				
429	13210	0001761-71-3	bis(4-aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	0001843-03-4	1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	yes	no	yes	5			
431	61600	0001843-05-6	2-hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)		
432	12280	0002035-75-8	adipic anhydride	no	yes	no				
433	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6			
434	20410	0002082-81-7	methacrylic acid, diester with 1,4-butanediol	no	yes	no	0,05			

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435	14230	0002123-24-2	caprolactam, sodium salt	no	yes	no	(4)			
436	19480	0002146-71-6	lauric acid, vinyl ester	no	yes	no				
437	11245	0002156-97-0	acrylic acid, dodecyl ester	no	yes	no	0,05	(2)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
438	38875	0002162-74-5	bis(2,6-diisopropylphenyl)carbodiimide	yes	no	no	0,05		For indirect food contact only, behind a PET layer	
439	21280	0002177-70-0	methacrylic acid, phenyl ester	no	yes	no		(23)		
440	21340	0002210-28-8	methacrylic acid, propyl ester	no	yes	no		(23)		
441	38160	0002315-68-6	benzoic acid, propyl ester	yes	no	no				
442	13780	0002425-79-8	1,4-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	(10)
443	12788	0002432-99-7	11-aminoundecanoic acid	no	yes	no	5			
444	61440	0002440-22-4	2-(2'-hydroxy-5'-methylphenyl)benzotriazole	yes	no	no		(12)		
445	83440	0002466-09-3	pyrophosphoric acid	yes	no	no				
446	10750	0002495-35-4	acrylic acid, benzyl ester	no	yes	no		(22)		
447	20080	0002495-37-6	methacrylic acid, benzyl ester	no	yes	no		(23)		
448	11890	0002499-59-4	acrylic acid, n-octyl ester	no	yes	no		(22)		
449	49840	0002500-88-1	dioctadecyl disulphide	yes	no	yes	3			
450	24430	0002561-88-8	sebacic anhydride	no	yes	no				
451	66755	0002682-20-4	2-methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions	
452	38885	0002725-22-6	2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	0,05		Only to be used in aqueous foods	

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453	26320	0002768-02-7	vinyltrimethoxysilane	no	yes	no	0,05			(10)
454	12670	0002855-13-2	1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6			
455	20530	0002867-47-2	methacrylic acid, 2-(dimethylamino)-ethyl ester	no	yes	no	ND			
456	10810	0002998-08-5	acrylic acid, sec-butyl ester	no	yes	no	(22)			
457	20140	0002998-18-7	methacrylic acid, sec-butyl ester	no	yes	no	(23)			
458	36960	0003061-75-4	behenamide	yes	no	no				
(1)	(1)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
459	459	0003135-18-0	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no	no				
460	460	0003173-53-3	cyclohexyl isocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety		(10)
461	461	0003173-72-6	1,5-naphthalene diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety		(10)
462	462	0003195-78-6	N-vinyl-N-methylacetamide	no	yes	no	0,02			(1)
463	463	0003290-92-4	1,1,1-trimethylolpropane trimethacrylate	no	yes	no	0,05			
464	464	0003293-97-8	2-hydroxy-4-n-hexyloxybenzophenone	yes	no	yes	(8)			
465	465	0003333-62-8	7-[2H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no				
466	466	0003648-18-8	di-n-octyltin dilaurate	yes	no	no	(10)			
467	467	0003724-65-0	crotonic acid	yes	yes	no	0,05			(1)
468	468	0003825-26-1	perfluorooctanoic acid, ammonium salt	yes	no	no	Only to be used in repeated use articles, sintered at high temperatures			

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469	469	0003864-99-1	2-(2'-hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes	(12)		
470	470	0003896-11-5	2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	yes	no	yes	(12)		
471	471	0003965-55-7	5-sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05		
472	472	0004066-02-8	2,2'-methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes	(5)		
473	473	0004074-90-2	adipic acid, divinyl ester	no	yes	no	ND	5 mg/kg in final product. Only to be used as co-monomer.	(1)
474	474	0004080-31-3	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3		
475	475	0004098-71-9	1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
476	16570	0004128-73-8	diphenylether-4,4'-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety
477	46720	0004130-42-1	2,6-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8		(1)
478	60180	0004191-73-5	4-hydroxybenzoic acid, isopropyl ester	yes	no	no			
479	12970	0004196-95-6	azelaic anhydride	no	yes	no			
480	46790	0004221-80-1	3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	yes	no	no			
481	13060	0004422-95-1	1,3,5-benzenetricarboxylic acid trichloride	no	yes	no	0,05	SML expressed as 1,3,5-benzenetricarboxylic acid	(1)
482	21100	0004655-34-9	methacrylic acid, isopropyl ester	no	yes	no	(23)		
483	68860	0004724-48-5	n-octylphosphonic acid	yes	no	no	0,05		

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484	13395	0004767-03-7	2,2-bis(hydroxymethyl) propionic acid	no	yes	no	0,05		(1)
485	13560 15700	0005124-30-1	dicyclohexylmethane-4,4'-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
486	54005	0005136-44-7	ethylene-N-palmitamide-N'-stearamide	yes	no	no			
487	45640	0005232-99-5	2-cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05		
488	53440	0005518-18-3	N,N'-ethylenebispalmitamide	yes	no	no			
489	41040	0005743-36-2	calcium butyrate	yes	no	no			
490	16600	0005873-54-1	diphenylmethane-2,4'-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
491	82720	0006182-11-2	1,2-propyleneglycol distearate	yes	no	no			
492	45650	0006197-30-4	2-cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	yes	no	no	0,05		
493	39200	0006200-40-4	bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy) methylammonium chloride	yes	no	no	1,8		
494	62140	0006303-21-5	hypophosphorous acid	yes	no	no			
495	35160	0006642-31-5	6-amino-1,3-dimethyluracil	yes	no	no	5		
496	71680	0006683-19-8	pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
497	95020	0006846-50-0	2,2,4-trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5	Only to be used in single-use gloves	
498	16210	0006864-37-5	3,3'-dimethyl-4,4'-diaminodicyclohexylmethane	no	yes	no	0,05	Only to be used in polyamides	(5)
499	19965	0006915-15-7	malic acid	yes	yes	no		In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis	
500	65020	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	yes	no	yes	0,6		

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501	34480	—	aluminium fibers, flakes and powders	yes	no	no	
502	22778	0007456-68-0	4,4'-oxybis(benzenesulphonyl azide)	no	yes	no	0,05 (1)
503	46080	0007585-20-0	β-dextrin	yes	no	no	
504	86240	0007631-86-9	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	0007631-90-5	sodium bisulphite	yes	no	no	(19)
506	86920	0007632-00-0	sodium nitrite	yes	no	no	0,6
507	59990	0007647-01-0	hydrochloric acid	yes	no	no	
508	86560	0007647-15-6	sodium bromide	yes	no	no	
509	23170	0007664-38-2	phosphoric acid	yes	yes	no	
510	<u>72640</u> 12789	0007664-41-7	ammonia	yes	yes	no	
511	35320 91920	0007664-93-9	sulphuric acid	yes	no	no	
512	81680	0007681-11-0	potassium iodide	yes	no	no	(6)
513	86800	0007681-82-5	sodium iodide	yes	no	no	(6)
514	91840	0007704-34-9	sulphur	yes	no	no	

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
515	26360 95855	0007732-18-5	water	yes	yes	no			In compliance with Directive 98/83/EC ⁽²⁾	
516	86960	0007757-83-7	sodium sulphite	yes	no	no		(19)		
517	81520	0007758-02-3	potassium bromide	yes	no	no				
518	35845	0007771-44-0	arachidonic acid	yes	no	no				
519	87120	0007772-98-7	sodium thiosulphate	yes	no	no		(19)		
520	65120	0007773-01-5	manganese chloride	yes	no	no				
521	58320	0007782-42-5	graphite	yes	no	no				
522	14530	0007782-50-5	chlorine	no	yes	no				
523	45195	0007787-70-4	copper bromide	yes	no	no				
524	24520	0008001-22-7	soybean oil	no	yes	no				
525	62640	0008001-39-6	japan wax	yes	no	no				
526	43440	0008001-75-0	ceresin	yes	no	no				
527	14411 42880	0008001-79-4	castor oil	yes	yes	no				
528	63760	0008002-43-5	lecithin	yes	no	no				
529	67850	0008002-53-7	montan wax	yes	no	no				
530	41760	0008006-44-8	candelilla wax	yes	no	no				
531	36880	0008012-89-3	beeswax	yes	no	no				
532	88640	0008013-07-8	soybean oil, epoxidised	yes	no	no	60 30(*)	(32) (*)	In the case of PVC gas-kets 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 by Directive 2006/125/EC, the SML is lowered to 30 mg/kg.Oxirane < 8 %, iodine number < 6.	

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
533	42720	0008015-86-9	carnauba wax	yes	no	no				
534	80720	0008017-16-1	polyphosphoric acids	yes	no	no				
535	24100 24130 24190 83840	0008050-09-7	rosin	yes	yes	no				
536	84320	0008050-15-5	rosin, hydrogenated, ester with	yes	no	no				
537	84080	0008050-26-8	rosin, ester with pentaerythritol	yes	no	no				
538	84000	0008050-31-5	rosin, ester with glycerol	yes	no	no				
539	24160	0008052-10-6	rosin tall oil	no	yes	no				
540	63940	0008062-15-5	lignosulphonic acid	yes	no	no	0,24	Only to be used as dispersant for plastics dispersions		
541	58480	0009000-01-5	gum arabic	yes	no	no				
542	42640	0009000-11-7	carboxymethylcellulose	yes	no	no				
543	45920	0009000-16-2	dammar	yes	no	no				
544	58400	0009000-30-0	guar gum	yes	no	no				
545	93680	0009000-65-1	tragacanth gum	yes	no	no				
546	71440	0009000-69-5	pectin	yes	no	no				
547	55440	0009000-70-8	gelatin	yes	no	no				
548	42800	0009000-71-9	casein	yes	no	no				
549	80000	0009002-88-4	polyethylene wax	yes	no	no				
550	81060	0009003-07-0	polypropylene wax	yes	no	no				
551	79920	0009003-11-6 0106392-12-5	poly(ethylene propylene) glycol	yes	no	no				

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552	81500	0009003-39-8	polyvinylpyrrolidone	yes	no	no	The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC ⁽³⁾				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	
553	<u>14500</u> 43280	0009004-34-6	cellulose	yes	yes	no					
554	43300	0009004-36-8	cellulose acetate butyrate	yes	no	no					
555	53280	0009004-57-3	ethylcellulose	yes	no	no					
556	54260	0009004-58-4	ethylhydroxyethylcellulose	yes	no	no					
557	66640	0009004-59-5	methylethylcellulose	yes	no	no					
558	60560	0009004-62-0	hydroxyethylcellulose	yes	no	no					
559	61680	0009004-64-2	hydroxypropylcellulose	yes	no	no					
560	66700	0009004-65-3	methylhydroxypropylcellulose	yes	no	no					
561	66240	0009004-67-5	methylcellulose	yes	no	no					
562	22450	0009004-70-0	nitrocellulose	no	yes	no					
563	78320	0009004-97-1	polyethyleneglycol monoricinoleate	yes	no	yes	42				
564	<u>24540</u> 88800	0009005-25-8	starch, edible	yes	yes	no					
565	61120	0009005-27-0	hydroxyethyl starch	yes	no	no					
566	33350	0009005-32-7	alginic acid	yes	no	no					
567	82080	0009005-37-2	1,2-propyleneglycol alginate	yes	no	no					
568	79040	0009005-64-5	polyethyleneglycol sorbitan monolaurate	yes	no	no					
569	79120	0009005-65-6	polyethyleneglycol sorbitan monooleate	yes	no	no					
570	79200	0009005-66-7	polyethyleneglycol sorbitan monopalmitate	yes	no	no					
571	79280	0009005-67-8	polyethyleneglycol sorbitan monostearate	yes	no	no					

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572	79360	0009005-70-3	polyethyleneglycol sorbitan trioleate	yes	no	no			
573	79440	0009005-71-4	polyethyleneglycol sorbitan tristearate	yes	no	no			
574	<u>24250</u> 84560	0009006-04-6	rubber, natural	yes	yes	no			
575	76721	0063148-62-9	Polydimethylsiloxane (Mw > 6 800 Da)	yes	no	no			Viscosity at 25 °C not less than 100 cSt ($100 \times 10^{-6} \text{ m}^2/\text{s}$)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
576	60880	0009032-42-2	hydroxyethylmethylcellulose	yes	no	no			
577	62280	0009044-17-1	isobutylene-butene copolymer	yes	no	no			
578	79600	0009046-01-9	polyethyleneglycol tridecyl ether phosphate	yes	no	no	5		For materials and articles intended for contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono-and dialkyl ester) with a maximum 10 % content of poly- ethyleneglycol (EO ≤ 11) tridecylether.
579	61800	0009049-76-7	hydroxypropyl starch	yes	no	no			
580	46070	0010016-20-3	α-dextrin	yes	no	no			
581	36800	0010022-31-8	barium nitrate	yes	no	no			
582	50240	0010039-33-5	di-n-octyltin bis(2-ethylhexyl maleate)	yes	no	no		(10)	
583	40400	0010043-11-5	boron nitride	yes	no	no		(16)	
584	<u>13620</u> 40320	0010043-35-3	boric acid	yes	yes	no		(16)	
585	41120	0010043-52-4	calcium chloride	yes	no	no			
586	65280	0010043-84-2	manganese hypophosphite	yes	no	no			
587	68400	0010094-45-8	octadecylceramide	yes	no	yes	5		
588	64320	0010377-51-2	lithium iodide	yes	no	no		(6)	

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589	52645	0010436-08-5	cis-11-eicosenamide	yes	no	no							
590	21370	0010595-80-9	methacrylic acid, 2-sulphoethyl ester	no	yes	no	ND						(1)
591	36160	0010605-09-1	ascorbyl stearate	yes	no	no							
592	34690	0011097-59-9	aluminium magnesium carbon- ate hydroxide	yes	no	no							
593	44960	0011104-61-3	cobalt oxide	yes	no	no							
594	65360	0011129-60-5	manganese oxide	yes	no	no							
595	19510	0011132-73-3	lignocellulose	no	yes	no							
596	95935	0011138-66-2	xanthan gum	yes	no	no							
	(1)	(2)	(3)	(4)			(5)	(6)	(7)	(8)	(9)	(10)	(11)
597		67120	0012001-26-2 mica				yes	no	(no 7)				
598		41600	0012004-14-7 calcium sulphoaluminate 0037293-22-4				yes	no	no				
599		36840	0012007-55-5 barium tetraborate				yes	no	no		(16)		
600		60030	0012072-90-1 hydromagnesite				yes	no	no				
601		35440	0012124-97-9 ammonium bromide				yes	no	no				
602		70240	0012198-93-5 ozokerite				yes	no	no				
603		83460	0012269-78-2 pyrophyllite				yes	no	no				
604		60080	0012304-65-3 hydrotalcite				yes	no	no				
605		11005	0012542-30-2 acrylic acid, dicyclopentenyl ester				no	yes	no	0,05			(1)
606		65200	0012626-88-9 manganese hydroxide				yes	no	no				
607		62245	0012751-22-3 iron phosphide				yes	no	no			Only to be used in PET polymers and copolymers	

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608	40800	0013003-12-8	4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecylphosphine)	yes	no	yes	6				
609	83455	0013445-56-2	pyrophosphorous acid	yes	no	no					
610	93440	0013463-67-7	titanium dioxide	yes	no	no					
611	35120	0013560-49-1	3-aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no					
612	16694	0013811-50-2	N,N'-divinyl-2-imidazolidinone	no	yes	no	0,05		(10)		
613	95905	0013983-17-0	wollastonite	yes	no	no					
614	45560	0014464-46-1	cristobalite	yes	no	no					
615	92080	0014807-96-6	talc	yes	no	no					
616	83470	0014808-60-7	quartz	yes	no	no					
617	10660	0015214-89-8	2-acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05				
618	51040	0015535-79-2	di-n-octyltin mercaptoacetate	yes	no	no		(10)			
619	50320	0015571-58-1	di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)			
620	50720	0015571-60-5	di-n-octyltin dimaleate	yes	no	no		(10)			
(1)	(2)	(3)	(4)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
621	17110	0016219-75-3	5-ethylidenebicyclo[2,2,1]hept-2-ene	5-ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	0016260-09-6	oleylpalmitamide	oleylpalmitamide	yes	no	yes	5			
623	52640	0016389-88-1	dolomite	dolomite	yes	no	no				
624	18897	0016712-64-4	6-hydroxy-2-naphthalenecarboxylic acid	6-hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	0017194-00-2	barium hydroxide	barium hydroxide	yes	no	no				
626	57800	0018641-57-1	glycerol tribehenate	glycerol tribehenate	yes	no	no				
627	59760	0019569-21-2	huntite	huntite	yes	no	no				
628	96190	0020427-58-1	zinc hydroxide	zinc hydroxide	yes	no	no				

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629	34560	0021645-51-2	aluminium hydroxide	aluminium hydroxide	yes	no	no			
630	82240	0022788-19-8	1,2-propyleneglycol dilaurate	1,2-propyleneglycol dilaurate	yes	no	no			
631	59120	0023128-74-7	1,6-hexamethylene-bis(3-(3,5- di-tert-butyl-4-hydroxyphenyl) propionamide)	1,6-hexamethylene-bis(3-(3,5- di-tert-butyl-4-hydroxyphenyl) propionamide)	yes	no	yes	45		
632	52880	0023676-09-7	4-ethoxybenzoic acid, ethyl ester	4-ethoxybenzoic acid, ethyl ester	yes	no	no	3,6		
633	53200	0023949-66-8	2-ethoxy-2'-ethyloxanilide	2-ethoxy-2'-ethyloxanilide	yes	no	yes	30		
634	25910	0024800-44-0	tripropyleneglycol	tripropyleneglycol	no	yes	no			
635	40720	0025013-16-5	tert-butyl-4-hydroxyanisole	tert-butyl-4-hydroxyanisole	yes	no	no	30		
636	31500	0025134-51-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	acrylic acid, acrylic acid2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22) SML expressed as acrylic acid, 2-ethylhexyl ester	
637	71635	0025151-96-6	pentaerythritol dioleate	pentaerythritol dioleate	yes	no	no	0,05	Not to be used for articles in contact with fatty foods for which simulant D is laid down	
638	<u>23590</u> 76960	0025322-68-3	polyethyleneglycol	polyethyleneglycol	yes	yes	no			
639	23651 80800	0025322-69-4	polypropyleneglycol	polypropyleneglycol	yes	yes	no			
640	54930	0025359-91-5	formaldehyde-1-naphthol, copolymer	formaldehyde-1-naphthol, copolymer	yes	no	no	0,05		
(1)	(1)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
641	641	0025513-64-8	mixture of (35-45 % w/w) 1,6-diamino-2,2,4- trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane	no	yes	no	0,05			(10)
642	642	0025736-61-2	maleic anhydride-styrene, copolymer, sodium salt	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w)	

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643	643	0026266-57-9	sorbitan monopalmitate	yes	no	no							
644	644	0026266-58-0	sorbitan trioleate	yes	no	no							
645	645	0026401-86-5	mono-n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no	(11)						
646	646	0026401-97-8	di-n-octyltin bis(isooctyl mercaptoacetate)	yes	no	no	(10)						
647	647	0026402-23-3	glycerol monohexanoate	yes	no	no							
648	648	0026402-26-6	glycerol mono-octanoate	yes	no	no							
649	649	0026427-07-6	dibutylthiostannoic acid polymer	yes	no	no	Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂)n (n = 1,5-2)						
650	650	0026636-01-1	dimethyltin bis(isooctyl mercaptoacetate)	yes	no	no	(9)						
651	651	0026658-19-5	sorbitan tristearate	yes	no	no							
652	652	0026741-53-7	bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	yes	no	yes	0,6						
653	653	0026747-90-0	2,4-toluene diisocyanate dimer	no	yes	no	(17)		1 mg/kg in final product expressed as isocyanate moiety			(10)	
654	654	0026836-47-5	sorbitol monostearate	yes	no	no							
655	655	0026896-48-0	tricyclodecanedimethanol	no	yes	no	0,05						
656	656	0026914-43-2	styrenesulphonic acid	no	yes	no	0,05						
657	657	0027107-89-7	mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	yes	no	no	(11)						
658	658	0027176-87-0	dodecylbenzenesulphonic acid	yes	no	no	30						
659	659	0027194-74-7	1,2-propyleneglycol monolaurate	yes	no	no							
660	660	0027458-90-8	di-tert-dodecyl disulphide	yes	no	yes	0,05						
	(1)	(2)	(3)	(4)			(5)	(6)	(7)	(8)	(9)	(10)	(11)
	661	95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione			yes	no	yes	5			
	662	25927	0027955-94-8	1,1,1-tris(4-hydroxyphenol) ethane			no	yes	no	0,005	Only to be used in polycarbonates		(1)

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663	64150	0028290-79-1	linolenic acid	yes	no	no	
664	95000	0028931-67-1	trimethylolpropane trimethacrylate-methyl methacrylate copolymer	yes	no	no	
665	83120	0029013-28-3	1,2-propyleneglycol monopalmitate	yes	no	no	
666	87280	0029116-98-1	sorbitan dioleate	yes	no	no	
667	55190	0029204-02-2	gadoleic acid	yes	no	no	
668	80240	0029894-35-7	polyglycerol ricinoleate	yes	no	no	
669	56610	0030233-64-8	glycerol monobehenate	yes	no	no	
670	56800	0030899-62-8	glycerol monolaurate diacetate	yes	no	no	(32)
671	74240	0031570-04-4	phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no	
672	76845	0031831-53-5	polyester of 1,4-butanediol with caprolactone	yes	no	no	(29) (30) The fraction with molecular weight below 1 000 Da should not exceed 0,5 % (w/w)
673	53670	0032509-66-3	ethylene glycol bis[3,3-bis(3- tert-butyl-4- hydroxyphenyl)butyrate]	yes	no	yes	6
674	46480	0032647-67-9	dibenzylidene sorbitol	yes	no	no	
675	38800	0032687-78-8	N,N'-bis(3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionyl)hy- drazide	yes	no	yes	15
676	50400	0033568-99-9	di-n-octyltin bis(isooctyl male- ate)	yes	no	no	(10)
677	82560	0033587-20-1	1,2-propyleneglycol dipalmitate	yes	no	no	
678	59200	0035074-77-2	1,6-hexamethylene-bis(3-(3,5-di- tert-butyl-4- hydroxyphenyl)propionate)	yes	no	yes	6
679	39060	0035958-30-6	1,1-bis(2-hydroxy-3,5-di-tert- butylphenyl)ethane	yes	no	yes	5

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
680	94400	0036443-68-2	triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	yes	no	no	9			
681	18310	0036653-82-4	1-hexadecanol	no	yes	no				
682	53270	0037205-99-5	ethylcarboxymethylcellulose	yes	no	no				
683	66200	0037206-01-2	methylcarboxymethylcellulose	yes	no	no				
684	68125	0037244-96-5	nepheline syenite	yes	no	no				
685	85950	0037296-97-2	silicic acid, magnesium-sodium-fluoride salt	yes	no	no	0,15		SML expressed as fluoride. Only to be used in layers of multi-layer materials not coming into direct contact with food.	
686	61390	0037353-59-6	hydroxymethylcellulose	yes	no	no				
687	<u>13530</u> 13614	0038103-06-9	2,2-bis(4-hydroxyphenyl) propane bis(phthalic anhydride)	no	yes	no	0,05			
688	92560	0038613-77-3	tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	yes	no	yes	18			
689	95280	0040601-76-1	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	6			
690	92880	0041484-35-9	thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	yes	no	yes	2,4			
691	13600	0047465-97-4	3,3-bis(3-methyl-4-hydroxyphenyl)2-indolinone	no	yes	no	1,8			
692	52320	0052047-59-3	2-(4-dodecylphenyl)indole	yes	no	yes	0,06			
693	88160	0054140-20-4	sorbitan tripalmitate	yes	no	no				
694	21400	0054276-35-6	methacrylic acid, sulphopropyl	no	yes	no	0,05			(1)

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ester										
695		67520	0054849-38-6	monomethyltin tris(isooctyl mercaptoacetate)	yes	no	no	(9)		
696		92205	0057569-40-1	terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	yes	no	no			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
697	67515	0057583-34-3	monomethyltin tris(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
698	49595	0057583-35-4	dimethyltin bis(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
699	90720	0058446-52-9	stearoylbenzoylmethane	yes	no	no				
700	31520	0061167-58-6	acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	yes	no	yes	6			
701	40160	0061269-61-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4			
702	87920	0061752-68-9	sorbitan tetrastearate	yes	no	no				
703	17170	0061788-47-4	fatty acids, coco	no	yes	no				
704	77600	0061788-85-0	polyethyleneglycol ester of hydrogenated castor oil	yes	no	no				
705	<u>10599/90A</u> 10599/91	0061788-89-4	acids, 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				

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707	46375	0061790-53-2	diatomaceous earth	yes	no	no				
708	77520	0061791-12-6	polyethyleneglycol ester of castor oil	yes	no	no	42			
709	87520	0062568-11-0	sorbitan monobehenate	yes	no	no				
710	38700	0063397-60-4	bis(2-carbobutoxyethyl)tin-bis (isooctyl mercaptoacetate)	yes	no	yes	18			
711	42000	0063438-80-2	(2-carbobutoxyethyl)tin-tris (isooctyl mercaptoacetate)	yes	no	yes	30			
712	42960	0064147-40-6	castor oil, dehydrated	yes	no	no				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
713	43480	0064365-11-3	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E153) set out by Commission Directive 95/45/EC ⁽⁴⁾ with exception of ash contents which can be up to 10% (w/w).	
714	84400	0064365-17-9	rosin, hydrogenated, ester with pentaerythritol	yes	no	no				
715	46880	0065140-91-2	3,5-di-tert-butyl-4- hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6			
716	60800	0065447-77-0	1-(2-hydroxyethyl)-4-hydroxy- 2,2,6,6-tetramethyl piperidine- succinic acid, dimethyl ester, copolymer	yes	no	no	30			
717	84210	0065997-06-0	rosin, hydrogenated	yes	no	no				
718	84240	0065997-13-9	rosin, hydrogenated, ester with glycerol	yes	no	no				
719	65920	0066822-60-4	N-methacryloyloxyethyl-N,N- dimethyl-N- carboxymethylammonium methacrylate-ethyl methacrylate- cyclohexyl methacrylate-N- vinyl-2-pyrrolidone, copolymers	yes	no	no				
720	67360	0067649-65-4	mono-n-dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no	(25)			
721	46800	0067845-93-6	3,5-di-tert-butyl-4- hydroxybenzoic acid, hexadecyl ester	yes	no	no				

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722	17200	0068308-53-2	fatty acids, soya	no	yes	no	
723	88880	0068412-29-3	starch, hydrolysed	yes	no	no	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8) (9) (10) (11)
724	24903	0068425-17-2	syrops, hydrolysed starch, hydrogenated	no	yes	no	In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ⁽⁵⁾
725	77895	0068439-49-6	polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether	yes	no	no	0,05 The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6)monoalkyl (C ₁₆ -C ₁₈) ether (approximately 28 %), — fatty alcohols (C ₁₆ -C ₁₈) (approximately 48 %), — ethyleneglycol monoalkyl (C ₁₆ -C ₁₈) ether (approximately 24 %),
726	83599	0068442-12-6	reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethylin	yes	no	yes	(9)
727	43360	0068442-85-3	cellulose, regenerated	yes	no	no	
728	75100	0068515-48-0	phthalic acid, diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than 60% C ₉	yes	no	no	(26) Only to be used as: (32) (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as

defined by Directive 2006/141/EC or pro- cessed 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										
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
729	75105	0068515-49-1 0026761-40-0	phthalic acid, diesters with primary, saturated C ₉ -C ₁₁ alcohols more than 90% C ₁₀	yes	no	no		(26) Only to be used as: (32) (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or pro- cessed cereal-based foods and baby foods or infants and young children as defined by Directive 2006/125/EC; (c) technical support agent in concentrations up to 0,1 % in the final product.		(7)
730	66930	0068554-70-1	methylsilsequioxane	yes	no	no		Residual monomer in methylsilsequioxane <1mg methyltrimethoxysilane/kg of methylsilsequioxane		
731	18220	0068564-88-5	N-heptylaminoundecanoic acid	no	yes	no	0,05			(2)
732	45450	0068610-51-5	p-cresol-dicyclopentadiene-isobutylene, copolymer	yes	no	yes	5			
733	10599/92A 10599/93	0068783-41-5	acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
734	46380	0068855-54-9	diatomaceous earth, soda ash flux-calcined	yes	no	no				
735	40120	0068951-50-8	bis(polyethyleneglycol)hydroxymethylphosphonate	---	---	---		0,6		

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736	50960	0069226-44-4	di-n-octyltin ethyleneglycol bis-(mercaptoacetate)	(10)						
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
737	77370	0070142-34-6	polyethyleneglycol-30 dipolyhydroxystearate	yes	no	no				
738	60320	0070321-86-7	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl] benzotriazole	yes	no	yes	1,5			
739	70000	0070331-94-1	2,2'-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
740	81200	0071878-19-8	poly[6-[(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	<u>24070</u> 83610	0073138-82-6	resin acids and rosin acids	yes	yes	no				
742	92700	0078301-43-6	2,2,4,4-tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5			
743	38950	0079072-96-1	bis(4-ethylbenzylidene)sorbitol	yes	no	no				
744	18888	0080181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no			The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in	

the Table 4 of Annex I

745	68145	0080410-33-9	2,2',2'-nitrilo(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	0080693-00-1	bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	yes	no	yes	5	SML expressed as sum of phosphite and phosphate		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(89)	(10)	(11)
747	47600	0084030-61-5	di-n-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes				
748	12765	0084434-12-8	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0.0%			
749	66360	0085209-91-2	2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5			
750	66350	0085209-93-4	2,2'-methylenebis (4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5			
751	81515	0087189-25-1	Poly (zinc glycerolate)	yes	no	no				
752	39890	0087826-41-3 0069158-41-4 0054686-97-4 0081541-12-0	Bis (methlbenzylidene) sorbitol	yes	no	no				
753	62800	0092704-41-1	Kaolin, calcined	yes	no	no				
754	56020	0099880-64-5	Glycerol dibehenate	yes	no	no				
755	21765	0106246-33-7	4,4'-methylenebis (3-chloro-2,6-diethylaniline)	no	yes	no	0.0%			(1)
756	40020	0110553-27-0	2,4-bis (octylthiomethyl)-6-methylphenol	yes	no	yes	(24)			
757	95725	0110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	yes	no	no				
758	38940	0110675-26-8	2,4-bis (dodecylthiomethyl)-6-methylphenol	yes	no	yes	(24)			
759	54309	0118337-09-0	2,2'-ethylidenebis (4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
760	83595	0119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	yes	no	no	18		Composition:	
									- 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl) phosphonite] (CAS No 0038613-77-3) (36-46% w/w (*)), - 4,3'-biphenylene-bis [0,0-bis(2,4-di-tert-butylphenyl) phosphonite] (CAS No 0118421-00-4) (17-23% w/w (*)). - 3,3'-biphenylene- bis[0,0-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- - 4,4'-biphenylene-0,0- bis(2,4-di-tert-butylphenyl) phosphonate-0,0- bis(2,4-di-tert-butylphenyl) phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*)) - (*) Quantity of substance used/quantity of formulation	

Other specification:

- Phosphor content of min. 5,4 to max, 10 mg KOH per gram,
- Melt range of 85-110°C

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
761	92930	0120218-34-0	thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	yes	no	no	6			
762	31530	0123968-25-2	acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester	yes	no	yes	5			
763	39925	0129228-21-3	3,3-bis(methoxymethyl)-2,5-dimethylhexane	yes	no	yes	0,05			
764	13317	0132459-54-2	N,N'-bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide	no	yes	no	0,05		Purity > 98,1 % w/w). Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT).	
765	49485	0134701-20-5	2,4-dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			
766	38879	0135861-56-2	bis(3,4-dimethylbenzylidene) sorbitol	yes	no	no				
767	38510	0136504-96-6	1,2-bis(3-aminopropyl) ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	yes	no	no	5			
768	34850	0143925-92-2	amines, bis(hydrogenated tallow alkyl) oxidised	yes	no	no			Not to be used for articles in contact with fatty foods for which simulant D is laid down. Only to be used in: (a) polyolefins at 0,1% (w/w) concentration and in (b) PET at 0.75% (w/w) concentration.	(1)
769	74010	0145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester.	yes	no	yes	5		SML expressed as sum of phosphate and phosphate	

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770	51700	0147315-50-2	2-(4,6-diphenyl-1,3,5-triazin-2-yl) -5(hexyloxy) phenol	yes	no	no	0.05		
771	34650	0151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
772	47500	0153250-52-3	N,N'-dicyclohexyl-2,6- naphthalene dicarboxamide	yes	no	no	5		
773	38840	0154862-43-8	bis(2,4-dicumylphenyl) pentaerythritol-diphosphite	yes	no	yes	5		SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl) pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)
774	95270	0161717-32-4	2,4,6-tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite		yes	no	yes	2	SML expressed as sum of phosphite, phosphate and the hydrolysis product = TTBP
775	45705	0166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)	
776	76723	0167883-16-1	polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 1,5 % (w/w)
777	31542	0174254-23-0	acrylic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters	yes	no	no			0,5 % in final product
778	71670	0178671-58-4	pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	yes	no	yes	0,05		
779	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0,05		(1)

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780	81220	0192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidiny)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	yes	no	no	5			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
781	95265	0227099-60-7	1,3,5-tris(4-benzoylphenyl) benzene	yes	no	no	0,05			
782	76725	0661476-41-1	polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 1 % (w/w)	
783	55910	0736150-63-3	glycerides, castor-oil mono-, hydrogenated, acetates	yes	no	no		(32)		
784	95420	0745070-61-5	1,3,5-tris (2,2-dimethylpropanamido) benzene	yes	no	no	0,05			
785	24910	0000100-21-0	terephthalic acid	no	yes	no		(28)		
786	14627	0000117-21-5	3-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3-chlorophthalic acid	
787	14628	0000118-45-6	4-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as	

4-chlorophthalic acid										
788	21498	0002530-85-0	[3-(methacryloxy)propyl] trimethoxysilane	no	yes	no	0,05	Only to be used as a surface treatment agent of inorganic fillers	(1) (11)	
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 molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10 ⁻⁶ m ² /s).	(2)	
790	80480	0090751-07-8 0082451-48-7	poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]]	yes	no	no	5	Average molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/kg, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg.	(16)	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
791	92470	0106990-43-6	N,N',N'',N'''-tetrakis(4,6-bis (N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl) amino)triazin-2-yl)-4,7-dichloro-1,3,5-triazine	yes	no	no	0,05			
792	92475	0203255-81-6	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid	yes	no	yes	5	SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products		
793	94000	0000102-71-6	triethanolamine	yes	no	no	0,05	SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine		

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794	18117	0000079-14-1	glycolic acid		no	yes	no			For indirect food contact only, behind a PET layer
795	40155	0124172-53-8	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine		yes	no	no	0,05	(2) (12)	
796	72141	0018600-59-4	2,2'-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]		yes	no	yes	0,05		SML including the sum of its hydrolysis products
797	76807	0007328-26-5	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol		yes	no	yes		(31) (32)	
798	92200	0006422-86-2	terephthalic acid, bis(2-ethylhexyl)ester		yes	no	no	60	(32)	
799	77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols		yes	no	no	1,8		In compliance with the purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1)
800	94425	0000867-13-0	triethyl phosphonoacetate		yes	no	no			Only for use in PET
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
801	30607	—	acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt	yes	no	no				
802	33105	0146340-15-0	alcohols, C ₁₂ -C ₁₄ secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5			(12)

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803	33535	0152261-33-1	α -alkenes(C ₂₀ -C ₂₄) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	yes	no	no			Not to be used for articles in contact with fatty foods for which simulant D is laid down. Not to be used in contact with alcoholic foods.	(13)
804	80510	1010121-89-7	poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzene-sulfonic 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 [ami-Notris (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	0001076-97-7	1,4-cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters	
807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles. Only to be used in PET bottles up to 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	0882073-43-0	bis(4-propylbenzylidene) propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
809	49080	0852282-89-4	N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)isoquinolin-1,3(2H)-dione	yes	no	yes	0,05		Only for use in PET	(6) (14) (15)
810	68119		neopentyl glycol, diesters and monoesters 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 simulant D is laid down.	
811	80077	0068441-17-8	polyethylene waxes, oxidised	yes	no	no	60			

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812	80350	0124578-12-7	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	yes	no	no			Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
813	91530	—	sulphosuccinic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts	yes	no	no	5		
814	91815	—	sulphosuccinic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts	yes	no	no	2		
815	94985	—	trimethylolpropane, mixed tri- esters 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 simulant D is laid
816	45704	—	cis-1,2-cyclohexanedicarboxylic acid,	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 poly ethylene in contact with acidic foods Purity ≥ 96 %
818	21530	—	methallylsulphonic acid, salts	no	yes	no	5		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
819	68110	—	Not to be used in polymers	yes	no	no	0,05			contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D is laid down. SML expressed as neodecanoic acid.
820	76420	—	pimelic acid, salts	yes	no	no				
821	90810	—	stearoyl-2-lactylic acid, salts	yes	no	no				

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822	71938	—	perchloric acid, salts	yes	no	no	0,05	(4)
823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5	
854	71943	0329238-24-6	perfluoro acetic acid, α -substituted with the copoly-mer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups	yes	no	no		Only to be used in concentrations up to 0,5 % w/w in the polymerization of fluoropolymers that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles
860	71980	0051798-33-5	perfluoro[2-(poly(n-propoxy))propanoic acid]	yes	no	no		Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
861	71990	0013252-13-6	perfluoro[2-(n-propoxy)propanoic acid]	yes	no	no		Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
862	15180	0018085-02-4	3,4-diacetoxy-1-butene	no	yes	no	0,05	SML including the hydrolysis product 3,4-dihydroxy-1-butene. Only for use as a co-monomer for ethyl vinyl alcohol copolymers.

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
864	46330	0000056-06-4	2,4-diamino-6-hydroxypyrimidine	yes	no	no	5		Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and	
865	40619	0025322-99-0	(butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 1 %	
866	40620	—	(butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 7 %	
867	40815	0040471-03-2	(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 %	
868	53245	0009010-88-2	(ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
869	66763	0027136-15-8	(butyl acrylate, methyl methacrylate, styrene) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 %	
870	95500	0160535-46-6	N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide	yes	no	no	5			
875	80345	0058128-22-6	poly(12-hydroxystearic acid) stearate	yes	no	yes	5			
878	31335	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C ₃ -C ₂₂)	yes	no	no				
879	31336	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C ₁ -C ₂₂)	yes	no	no				

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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
880	31348	0085116-93-4	acids, fatty (C ₈ -C ₂₂), esters with pentaerythritol	yes	no	no				
881	25187	0003010-96-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for repeated use articles for long term storage at room temperature or below and hotfill	
882	25872	0002416-94-6	2,3,6-trimethylphenol	no	yes	no	0,05			
883	22074	0004457-71-0	3-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	
884	34240	0091082-17-6	alkyl(C ₁₀ -C ₂₁)sulphonic acid, esters with phenol	yes	No	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down.	
885	45676	0263244-54-8	cyclic 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 term storage at room temperature>	

(¹) OJL 302, 19.11.2005, p. 28. (²) OJL 330, 5.12.1998, p. 32. (³) OJL 253, 20.9.2008, p. 1. (⁴) OJL 226, 22.9.1995, p. 1. (⁵) OJ L 158, 18.6.2008, p.

5.2 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 Appendix.

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 Appendix.

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.

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 Appendix.

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 Appendix.

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

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

Table (2)

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

	464		
9	650	0.18	Expressed as tin
	695		
	697		
	698		
	720		

(1)	(2)	(3)	(4)
10	28	0.006	Expressed as tin
	29		
	30		
	31		
	32		
	33		
	466		
	582		
	618		
	619		
	620		
	646		
	676736		
11	66	1.2	Expressed as tin
	645		
	657		
12	444	30	Expressed as the sum of substances
	469		

	470		
13	163 285	1.5	Expressed as the sum of substances
14	294 368	5	Expressed as the sum of substances
15	98 196	15	Expressed as formaldehyde
16	407 583 584 599	6	Expressed as boron without prejudice to the provisions of Directive 98/83/EC
17	4 167 169 198 274 354 372 460 461 475 476 485 490 653	ND	Expressed as isocyanate moiety
18	705	0.05	Expressed as the some of the substances

	733		
19	505 516 519	10	Expressed as SO ₂
20	290 386 390	30	Expressed as the sum of substances
21	347 349	5	Expressed as trimellitic acid
2	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	Expressed as acryloic acid
23	150 156 181	6	Expressed as methacrylic acid

	183		
	184		
	355		
	370		
	374		
	439		
	440		
	447		
	457		
	482		
24	756 758	5	Expressed as the sum of 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 substances
27	188 291	5	Expressed as isophthalic acid
28	191 192 785	7.5	Expressed as terephthalic acid
29	342 672	0.05	Expressed as the sum of 6-hydroxyhexanoic acid and caprolactone

30	254	5	Expressed as 1,4-butanediol
	672		
31	73	30	Expressed as the sum of substances
	797		
32	8	60	Expressed as the sum of substances
	72		
	72		
	138		
	140		
	157		
	159		
	207		
	242		
	283		
	532		
	670		
	728		
	729		
	775		
	783		
	797		
	798		
	810		
	815		

5.3 Notes on verification of compliance

Table 3 : 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 Appendix.

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

Table (3):

(1)	(2)
Note No.	Notes on verification of compliance
(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Section 3(1)c of the General Regulation.
(4)	Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D
(5)	Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D2 (unstable)
(6)	Migration limit might be exceeded at very high temperature.
(7)	If testing in food is performed, Appendix 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
(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 stimulant
(11)	Only a method of analysis for the determination of the residual monomer in the treated filler is available
(12)	There is a risk that the SML could be exceeded from polyolefins.
(13)	Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available
(14)	There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance
(15)	There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.
(16)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods
(17)	Only a method for determination of the residual content of the substance in the polymer is available

5.4 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 Appendix I to which the specification applies.

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

Table (4)

(1)		(2)
FCM Substance No.		Detailed specification on the substance
744	Definition	The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of

		glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	0080181-31-3
	Structural formula	$ \begin{array}{ccccccc} & & & & \text{CH}_3 & & \\ & & & & & & \\ \text{CH}_3 & & \text{O} & & \text{CH}_2 & & \text{O} \\ & & & & & & \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n \end{array} $ where $n/(m + n)$ greater than 0 and less or equal to 0,25
	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay	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
	Restriction	QMA for crotonic acid is 0.05 mg/6 dm
	Purity	Prior to granulation the raw material copolymer powder must contain:
	- nitrogen,	Not more than 2 500 mg/kg of plastic
	- zinc,	Not more than 100 mg/kg of plastic
	- copper,	Not more than 5 mg/kg of plastic
	- lead,	Not more than 2 mg/kg of plastic
	- arsenic,	Not more than 1 mg/kg of plastic
	- chromium.	Not more than 1 mg/kg of plastic

Tests shall be carried out according to GSO standard stated in item 2.2.

7- Transportation and Storage:

7.1 They shall be transported and stored under suitable conditions, far from direct sunlight, and high temperatures and relative humidity, in addition to contamination sources.

8- LABELLING:

8.1 It is mandatory that the food grade sign  is posted on plastic or plastic-padded packing and packaging materials directly in contact with food.

8.2 The following labelling information shall be written on labels of plastic packages that are used to package food materials:

8.2.1 Type of plastic material.

8.2.2 Weight, capacity, number, or dimensions based on the type of packages.

8.2.3 Purpose and type of application.

8.2.4 Directions for usage.

8.2.5 Warnings if applicable.

References:

- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food