

ANNEX

Annex I to Regulation (EU) No 10/2011 is amended as follows:

(1) Table 1 is amended as follows:

(a) the entries concerning FCM substances Nos 161, 241, 344, 364, 410, 713, 784, 799, 880 and 881 are replaced by the following:

161	92160	00008	7-69-4 (+)-tartaric acid	yes	no	no				
241	22960	00001	08-95-2 phenol	no	yes	no	3			
344	13810	00005	05-46-7 butanediol formal	no	yes	no	0,05	15 30		(21)
	21821									
364	15404	00006	52-46-6 dianhydrosorbitol	no	yes	no	5		Only to be used as:	
									(a)	a co-monomer in poly(ethylene-co-isosorbide terephthalate);
									(b)	a co-monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol

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

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									and/ or 1,4- bis(hydroxymethyl)cycl for the production of polyesters. Polyesters made using dianhydrosorbitol together with 1,4- bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol.
410	62720	00013	32-58-7	no	yes	no	no		Particles can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene

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									vinyl alcohol copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food.
713	43480	00643	Charcoal, activated	no	no				Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon

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									(E 153) set out by Commission Regulation (EU) No 231/2012 ^a with exception of ash content which can be up to 10 % (w/w).
784	95420	07450	70361-5	yes	no	no	5		
			tris (2,2-dimethylpropanamido) benzene						
799	77708		polyethylene glycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation

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								(EU) No 231/2012.	
880	31348		acids, fatty (C ₈ -C ₂₂), esters with pentaerythritol'	yes	no	no			
881	25187	00030	0296.4 tetramethylcyclobutane-1,3-diol	no	yes	no	5	Only for: (a)	repeated use articles for long term storage at room temperature or below and hotfill; single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of
								(b)	

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										polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such
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a Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

										single use materials and articles.
a	Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1). ⁷									

(b) the following entries are inserted in numerical order of the FCM substance numbers:

859			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	yes	no	no				Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/or the substance
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								with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
903	37486-20-4	yes	no	no				Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for: (a) repeated and single
		perfluoro-[(5,8,11,14-tetraethylpropyl ether)]-tetraethyleneglycol						

									use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times;
969	24937	78-8 vinyl	no	no				(b)	repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes.

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		acetate copolymer wax					used as a polymeric additive up to 2 % w/w in polyolefins. The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/kg food.
998		(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including

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1017		25618-55-7	polyglycerol	no	no			To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with

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30	254 344 672	5	expressed as 1,4-butanediol
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(3) In Table 3, the following entry is added:

(21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.
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