

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 1282/2011, ANNEX. (See end of Document for details)

ANNEX

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

- (1) in Table 1 the following lines are inserted in numerical order of the FCM substance numbers:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (Group restriction No)	Restrictions and specifications	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
855	40560		(butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.	
856	40563		(butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level	

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			or 1,3- butanediol dimethacrylate					of 12 % at room temperature or below.
857	66765	003795	vinyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % at room temperature or below.
863	15260	000064	1,3- decanediamine	no	yes	no	0,05	Only to be used as a co- monomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact

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									up to 150 °C.
873	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no			Reaction product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures.
894	93360	001654	5-14-11 propionic acid, ditetradecyl ester	no	no		(14)		
895	47060	017109	0-93-0 (3,5-di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols	yes	no	no	0,05		Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products.
896	71958	095844	3-14-8 perfluoro-3-[(3-methoxypropoxy)propanoic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers when: — processed at temperatures

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										higher than 280 °C for at least 10 minutes, processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles.
923	39150	000012040	N,N-bis(2-hydroxyethyl)dodecanamide	yes	no	no	5			(18) The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, should not result in a migration of

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								diethanolamine higher than 0,3 mg/ kg food.
924	94987		trimethylpropane, mixed triesters and diesters with n- octanoic and n- decanoic acids	no	no	0,05		Only for use in PET in contact with all types of foods other than fatty, high- alcoholic and dairy products.
926	71955	0908020	perfluoro(2- ethoxy- ethoxy)acetic acid], ammonium salt	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes.
971	25885	0002459	trimellitic anhydride	yes	no			Only to be used as a co- monomer up to (17)

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									0,35 % w/ w to produce modified polyesters intended to be used in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158	58-74-6 copper hydroxide phosphate	yes	no	no			
973	22931	0019430	09354-0 perfluoro- n-butyl methacrylate	no	yes	no			Only to be used as a co- monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.
974	74050	939402	112-53-0 phosphoric acid, mixed 2,4- bis(1,1- dimethylpropyl)phenyl and 4- (1,1-	yes	no	yes	5		SML expressed as the sum of phosphite and phosphate form

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			dimethylpropyl)phenyl triesters							of the substance and the hydrolysis product 4-t-amyphenol. The migration of the hydrolysis product 2,4-di-t-amyphenol should not exceed 0,05 mg/kg.
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(2) in Table 1 for the following substance, the content of the columns (2), (5), (6) and (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (no)	SML (mg/kg) (yes/no)	SML (mg/kg) (Group restriction No)	Restrictions and specificities	Notes on certification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
438	13303	0002162-3	bis(2,6-diisopropylphenyl)carbodiimide	no	yes	no	0,05		Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product	

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										2,6-diisopropylaniline
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- (3) in Table 1 for the following substance, the content of the column (3) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (no)	SML (yes/kg)	SML (mg/kg) (Group restriction No)	Restrictions and specifications	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
797	76807	007301	polyesters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		

- (4) in Table 1 for the following substances, the content of the column (8) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (no)	SML (yes/kg)	SML (mg/kg) (Group restriction No)	Restrictions and specifications	Notes on compliance
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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
239	19975	0000102-48-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
	25420									
	93720									
376	66905	0000872-50-4	1-methylpyrrolidone	yes	no	no	60			

(5) in Table 1 for the following substance, the content of the columns (8) and (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (Group restriction No)	Restrictions and specificities	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
452	38885	0002722-42-6	bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	5			

(6) in Table 1 for the following substances, the content of the column (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (Group restriction No)	Restrictions and specificities	Notes on compliance
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(1)	(2)	(3)	(4)	(5)	obtained from microbial fermentation (yes/ no)	(7)	(8)	(9)	(10)	(11)
794	18117	000007914	glycolic acid	no	yes	no			Only to be used for manufacture of polyglycolic acid (PGA) for (i) indirect food contact behind polyesters such as polyethylene terephthalate (PET) or polylactic acid (PLA); and (ii) direct food contact of a blend of PGA up to 3 % w/ w in PET or PLA.	
812	80350	012457812	poly(12- hydroxystearic acid)- polyethyleneimine copolymer	yes	no	no			Only to be used in plastics up to	

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										0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
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(7) in Table 1 for the following substance, the content of the columns (10) and (11) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (no)	SML (mg/kg) (yes/no)	SML (Group restriction No)	Restrictions and specificities	Notes on certification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
862	15180	0018083-02-4	3,4-diacetoxy-1-butene	no	yes	no	0,05		SML including the hydrolysis product 3,4-dihydroxy-1-butene. Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.	(17) (19)

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- (8) in Table 2 for the following group restriction, the content of the columns (2) and (4) is replaced by the following:

Group restriction No	FCM substance No	SML (T)[mg/kg]	Group restriction specification
(1)	(2)	(3)	(4)
14	294	5	Expressed as the sum of the substances and their oxidation products
	368		
	894		

- (9) in Table 3 the following notes on verification of compliance are inserted in numerical order:

Note No	Notes on verification of compliance
(1)	(2)
(18)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)
(19)	There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers

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