

[^{XI}ANNEX III

Editorial Information

- XI** Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

Annex III to Directive 2002/72/EC is amended as follows:

(1) Section A is amended as follows:

(a) the following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
38885	002725-22-6	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	SML = 0,05 mg/kg. For aqueous foods only.
42080	001333-86-4	Carbon black	In compliance with the specifications laid down in Annex V.
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	
62020	007620-77-1	12-Hydroxystearic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as lithium)
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n-octyl ester.	SML = 5 mg/kg ⁽¹⁾

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71960	003825-26-1	Perfluorooctanoic acid, ammonium salt	Only to be used in repeated use articles, sintered at high temperatures.
74560	000085-68-7	Phthalic acid, benzyl butyl ester	To be used only as: <ul style="list-style-type: none"> (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to

			0,1 % in the final product. SML = 30 mg/kg food simulant.
74640	000117-81-7	Phthalic acid, bis (2-ethylhexyl) ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non- fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product. SML = 1,5 mg/kg food simulant.
74880	000084-74-2	Phthalic acid, dibutyl ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non- fatty foods; (b) technical support agent in polyolefines in concentrations

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			up to 0,05 % in the final product. SML = 0,3 mg/kg food simulant.
75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than 60 % C ₉ .	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent

			in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ⁽⁴²⁾ .
75105	068515-49-1 026761-40-0	Phthalic acid, diesters with primary, saturated C ₉ -C ₁₁ alcohols more than 90 % C ₁₀	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC;

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			(c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ⁽⁴²⁾ .
79920	009003-11-6 106392-12-5	Poly(ethylene propylene) glycol	
81500	9003-39-8	Polyvinylpyrrolidone	In compliance with the specifications laid down in Annex V.
93760	000077-90-7	Tri-n-butyl acetyl citrate	
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	SML = 5 mg/kg food. To be used in single-use gloves only.
95420	745070-61-5	1,3,5-tris (2,2-dimethylpropanamido)benzene	SML = 0,05 mg/kg food

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
43480	064365-11-3	Charcoal, activated	In compliance with the specifications laid down in Annex V.
45200	001335-23-5	Copper iodide	SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as copper) and SML = 1 mg/kg ⁽¹¹⁾ (expressed as iodine)

76845	031831-53-5	Polyester of 1,4-butanediol with caprolactone	The restriction for Ref. No 14260 and Ref. No 13720 shall be respected. In compliance with the specifications laid down in Annex V.
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 5 mg/kg (⁷) (expressed as copper); SML = 48 mg/kg (expressed as iron)
88640	008013-07-8	Soybean oil, epoxidised	SML = 60 mg/kg. However in the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 91/321/EEC or containing processed cereal-based foods and baby foods for infants and young children as defined by Directive 96/5/EC, the SML is lowered to 30 mg/kg. In compliance with the specifications laid down in Annex V. ⁷

(c) the following additive is deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
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(1)	(2)	(3)	(4)
'35760	001309-64-4	Antimony trioxide	SML = 0,04 mg/kg ⁽³⁹⁾ (expressed as antimony).'

(2) Section B is amended as follows:

(a) the following additives are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'35760	001309-64-4	antimony trioxide	SML = 0,04 mg/kg ⁽³⁹⁾ (expressed as antimony)
47500	153250-52-3	N,N'-Dicyclohexyl-2,6-naphthalene dicarboxamide	SML = 5 mg/kg.
72081/10	—	Petroleum hydrocarbon resins (hydrogenated)	SML = 5 mg/kg ⁽¹⁾ and in compliance with the specifications laid down in Annex V
93970	—	Tricyclodecanedimethane bis(hexahydrophthalate)	SML = 0,05 mg/kg

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ⁽⁴¹⁾ (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate),

			mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ⁽⁴¹⁾ (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride'

(c) The following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.	SML = 5 mg/kg ⁽¹⁾
76681	—	Polycyclopentadiene hydrogenated	SML = 5 mg/kg ⁽¹⁾