

ANNEX III

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⁾
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: (a) plasticizer in

Status: This is the original version (as it was originally adopted).

			<p>repeated use materials and articles; 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;</p> <p>(b)</p> <p>(c) technical support agent in concentrations up to 0,1 % in the final product.</p> <p>SML = 30 mg/kg food simulant.</p>
74640	000117-81-7	Phthalic acid, bis (2-ethylhexyl) ester	To be used only as:

			<p>(a) plasticizer in repeated use materials and articles contacting non-fatty foods;</p> <p>(b) technical support agent in concentrations up to 0,1 % in the final product.</p> <p>SML = 1,5 mg/kg food simulant.</p>
74880	000084-74-2	Phthalic acid, dibutyl ester	<p>To be used only as:</p> <p>(a) plasticizer in repeated use materials and articles contacting non-fatty foods;</p> <p>(b) technical support agent in polyolefines in concentrations up to 0,05 % in the final product.</p> <p>SML = 0,3 mg/kg food simulant.</p>

Status: This is the original version (as it was originally adopted).

75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than 60 % C ₉ .	<p>To be used only as:</p> <p>(a) plasticizer in repeated use materials and articles;</p> <p>(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;</p> <p>(c) technical support agent in concentrations up to 0,1 % in the final product.</p>
-------	----------------------------	--	---

			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; (c) technical support agent in concentrations up to 0,1 % in the

Status: This is the original version (as it was originally adopted).

			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.?

(c) the following additive is deleted:

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).?

(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⁾