

COMMISSION DIRECTIVE 1999/91/EC
of 23 November 1999
amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs
 (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs ⁽¹⁾ and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 90/128/EEC ⁽²⁾, as last amended by Directive 96/11/EC ⁽³⁾, provides in Article 3(2) for the revision of Annex II thereto.
- (2) On the basis of the information available, certain monomers provisionally admitted at national level may be included in the Community list.
- (3) Other monomers have been requested for use following the adoption of Directive 90/128/EEC: the technical data supplied permit their inclusion in the Community list.
- (4) Annex III to Directive 90/128/EEC includes a list of additives, which should be amended so as to include other additives fully evaluated by the Scientific Committee on Food.
- (5) For certain substances, the restrictions already set out should be amended according to the information available.
- (6) The current total list of additives is an incomplete list inasmuch as it does not contain all the substances which are currently accepted in one or more Member States; accordingly, these substances continue to be regulated by national laws pending a decision on inclusion in the Community list.
- (7) This Directive establishes purity criteria for only a few substances, and therefore the other substances which may require purity criteria remain regulated in this respect by national laws pending a decision at Community level.
- (8) The measures contained in this Directive do not go beyond what is necessary to achieve the objectives already provided for in Directive 89/109/EEC.

- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/128/EEC is amended as follows:

1. the fourth indent of Article 3(5) is deleted;
2. Article 3a is replaced by the following:

'Article 3a

An incomplete list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions on their use, is set out in Annex III';

3. the following Articles 3b and 3c are inserted:

'Article 3b

Only the products obtained by means of bacterial fermentation listed in Annex IV may be used in contact with foodstuffs.

Article 3c

1. The specifications relating to some substances appearing in Annexes II, III and IV are laid down in Annex V.

2. The meaning of the numbers between brackets appearing in the Column "Restrictions and/or specifications" is explained in Annex VI';

4. Annex II is amended as shown in Annex I to this Directive;
5. Annex III is amended as shown in Annex II to this Directive;
6. the texts set out in Annex III to this Directive are added as Annexes IV, V and VI.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 2000. They shall immediately inform the Commission thereof.

Member States shall permit, as from 1 January 2002, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive.

They shall prohibit, as from 1 January 2003, the manufacture and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.

⁽¹⁾ OJ L 40, 11.2.1989, p. 38.

⁽²⁾ OJ L 75, 21.3.1990, p. 19.

⁽³⁾ OJ L 61, 12.3.1996, p. 26.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 November 1999.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX I

Annex II is amended as follows:

1. The fourth indent of paragraph 5 is replaced by the following:
 - Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer;
2. The title of column 4 is modified to 'Restrictions and/or specifications';
3. Sections A and B are amended as shown in Appendices 1 to 5.

Appendix 1

List of monomers and other starting substances inserted in Section A of Annex II to Directive 90/128/EEC

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
12761	000693-57-2	12-Aminododecanoic acid	SML = 0,05 mg/kg
13180	000498-66-8	Bicyclo[2.2.1]hept-2-ene (= norbornene)	SML = 0,05 mg/kg
13210	001761-71-3	Bis(4-aminocyclohexyl)methane	SML = 0,05 mg/kg
14650	000079-38-9	Chlorotrifluoroethylene	QMA = 0,05 mg/6 dm ²
14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
16694	013811-50-2	N,N'-Divinyl-2-imidazolidinone	QM = 5 mg/kg in FP
16704	000112-41-4	1-Dodecene	SML = 0,05 mg/kg
22331	025513-64-8	Mixture of (40 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²
22550	000498-66-8	Norbornene	See "Bicyclo[2.2.1]hept-2-ene"
23175	000122-52-1	Phosphorous acid, triethyl ester	QM = ND (DL = 1 mg/kg in FP)
23547	009016-00-6 063148-62-9	Polydimethylsiloxane (MW > 6800)	In compliance with the specifications laid down in Annex V
25080	001120-36-1	1-Tetradecene	SML = 0,05 mg/kg
25385	000102-70-5	Triallylamine	In compliance with the specifications laid down in Annex V
25927	027955-94-8	1,1,1-Tris(4-hydroxyphenyl)ethane	QM = 0,5 mg/kg in FP. For use only in polycarbonates
26155	001072-63-5	1-Vinylimidazole	QM = 5 mg/kg in FP
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
26360	007732-18-5	Water	In compliance with Directive 98/83/EC

Appendix 2

List of monomers and other starting substances in Section A of Annex II to Directive 90/128/EEC for which the content of the column "Restriction and/or specifications" is modified

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
10060	000075-07-0	Acetaldehyde	SML(T) = 6 mg/kg (2)
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE)	SML(T) = 1 mg/kg (9) Authorised until 1 January 2005
14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)
14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg (5) (expressed as caprolactam)
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg (3)
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg (3)
17160	000097-53-0	Eugenol	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg (4)
19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg (4) (expressed as maleic acid)
25360	—	Trialkyl(C5-C15) acetic acid, 2,3-epoxypropyl ester	QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43)

Appendix 3

List of monomers and others starting substances deleted from Section B of Annex II to Directive 90/128/EEC

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
22428	051000-52-3	Neodecanoic acid, vinyl ester	

Appendix 4

List of monomers and other starting substances in Section B of Annex II to Directive 90/128/EEC for which the content of the column "Restrictions and/or specifications" is modified

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
16690	001321-74-0	Divinylbenzene	QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QM(T) = 5 mg/kg in FP (expressed as epoxy group, molecular weight = 43)
22720	000140-66-9	4-tert-Octylphenol	See "4-(1,1,3,3-Tetramethylbutyl)phenol"
25185	000140-66-9	4-(1,1,3,3-Tetramethylbutyl)phenol (= 4-tert-Octylphenol)	SML = ND (DL = 0,01 mg/kg, analytical tolerance included)

Appendix 5

List of monomers and other starting substances transferred from Section B to Section A of Annex II to Directive 90/128/EEC

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	QMA = 0,05 mg/6 dm ²
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg (1)
12265	004074-90-2	Adipic acid, divinyl ester	QM = 5 mg/kg in FP. For use only as comonomer
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	QMA = 0,05 mg/6 dm ² (measured as 1,3,5-benzenetricarboxylic acid)
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43)
14020	000098-54-4	4-tert-Butylphenol	SML = 0,05 mg/kg
15130	000872-05-9	1-Decene	SML = 0,05 mg/kg
16360	000576-26-1	2,6-Dimethylphenol	SML = 0,05 mg/kg
16450	000646-06-0	1,3-Dioxolane	SML = 0,05 mg/kg
18220	068564-88-5	N-Heptylamino undecanoic acid	SML = 0,05 mg/kg (1)
18820	000592-41-6	1-Hexene	SML = 3 mg/kg
19060	000109-53-5	Isobutyl vinyl ether	QM = 5 mg/kg in FP
19150	000121-91-5	Isophthalic acid	SML = 5 mg/kg
19990	000079-39-0	Methacrylamide	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20050	000096-05-9	Methacrylic acid, allyl ester	SML = 0,05 mg/kg
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
21730	000563-45-1	3-Methyl-1-butene	QMA = 0,006 mg/6 dm ² . For use only in polypropylene.
22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	SML = 0,05 mg/kg
23770	000504-63-2	1,3-Propanediol	SML = 0,05 mg/kg
23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)
24760	026914-43-2	Styrenesulphonic acid	SML = 0,05 mg/kg
26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 2 mg/kg in FP'

ANNEX II

Annex III is amended as follows:

1. The fourth indent of paragraph 5 is replaced by the following:
 - Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or to the polymer;
2. The title of the column 4 is modified into 'Restrictions and/or specifications';
3. 'Incomplete list of additives' is amended as shown in Appendices 1, 2 and 3.

'Appendix 1

List of additives inserted in Annex III to Directive 90/128/EEC

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
30080	004180-12-5	Acetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
30610	—	Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	
30612	—	Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic, and their mono-, di- and triglycerol esters	
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]phenyl ester	SML = 5 mg/kg
33801	—	n-Alkyl(C10-C13)benzenesulphonic acid	SML = 30 mg/kg
34240	—	Alkyl(C10-C20)sulphonic acid, esters with phenols	SML = 6 mg/kg. Authorised until 1 January 2002
36640	000123-77-3	Azodicarbonamide	For use only as a blowing agent
37360	000100-52-7	Benzaldehyde	In compliance with note 10 in Annex VI
38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene	In compliance with the specifications laid down in Annex V

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
38510	136504-96-6	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	SML = 5 mg/kg
38515	001533-45-5	4,4-Bis(2-benzoxazolyl)stilbene	SML = 0,05 mg/kg (1)
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	SML = 5 mg/kg (sum of phosphite and phosphate)
38879	135861-56-2	Bis(3,4-dimethylbenzylidene)sorbitol	
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	SML = 1,8 mg/kg
39815	182121-12-6	9,9-Bis(metoxymethyl)fluorene	QMA = 0,05 mg/6 dm ²
40120	—	Bis(polyethyleneglycol)hydroxymethylphosphonate	SML = 0,6 mg/kg. Authorised until 1 January 2002
41680	000076-22-2	Camphor	In compliance with note 10 in Annex VI
42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg (7) expressed as copper)
43515	—	Chlorides of choline esters of coconut oil fatty acids	QMA = 0,9 mg/6 dm ²
45195	007787-70-4	Copper bromide	SML(T) = 30 mg/kg (7) (expressed as copper)
45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg (7) (expressed as copper) and SML = 1 mg/kg (expressed as iodine)
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 0,05 mg/kg (1)
46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt	SML = 6 mg/kg
47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg (3)
48460	000075-37-6	1,1-Difluoroethane	
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	SML = 1 mg/kg
51700	147315-50-2	2-(4,6-Dphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	SML = 0,05 mg/kg
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper	SML(T) = 30 mg/kg (7) (expressed as copper)

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
53650	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg (3)
54300	118337-09-0	2,2'Ethylidenebis(4,6-di-tert-butyl-phenyl) fluorophosphonite	SML = 6 mg/kg
54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [=Poly(1-hydroxynaphthyl-methane)]	SML = 0,05 mg/kg
57800	018641-57-1	Glycerol tribehenate	
60480	003864-99-1	2-(2-Hidroxy-3,5-di-tert-butyl-phenyl)-5-chlorobenzotriazole	SML = 30 mg/kg
66560	004066-02-8	2,2'Methylenebis(4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg (6)
66580	000077-62-3	2,2'Methylenebis[4-methyl-6-(1-methylcyclo-hexyl)phenol]	SML(T) = 3 mg/kg (6)
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = ND (LD = 0,02 mg/kg, analytical tolerance included)
67170	—	Mixture of (80 to 100 % w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0 to 20 % w/w) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-2(3H)-benzofuranone	SML = 5 mg/kg
67180	—	Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester	SML = 5 mg/kg (1)
68145	080410-33-9	2,2',2''-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite]	SML = 5 mg/kg (sum of phosphite and phosphate)
71635	025151-96-6	Pentaerythritol dioleate	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
73720	000155-96-8	Phosphoric acid, trichloroethyl ester	SML = ND (LD = 0,02 mg/kg, analytical tolerance included)
74010	145650-60-8	Phosphorous acid, bis (2,4-di-tert-butyl-6-methylphenyl) ethyl ester	SML = 5 mg/kg (sum of phosphite and phosphate)
76721	009016-00-6 063148-62-9	Polydimethylsiloxane (MW > 6800)	In compliance with the specifications laid down in Annex V
76865	—	Polyesters of 1,2-propanediol and/or 1,3- and 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol	SML = 30 mg/kg

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
77895	068439-49-6	Polyethyleneglycol(EO = 2-6) mono-alkyl(C16-C18) ether	SML = 0,05 mg/kg
81515	087189-25-1	Poly(zinc glycerolate)	
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 30 mg/kg (7) (expressed as copper); SML = 48 mg/kg (expressed as iron)
85360	000109-43-3	Sebacic acid, dibutyl ester	
85610	—	Silicates, natural, silanated (with the exception of asbestos)	
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0,6 mg/kg (8) (expressed as lithium)
86285	—	Silicon dioxide, silanated	
88640	008013-07-8	Soybean oil, epoxidised	In compliance with the specifications laid down in Annex V
89200	007617-31-4	Stearic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
89440	—	Stearic acid, esters with ethylene-glycol	SML(T) = 30 mg/kg (3)
92030	010124-44-4	Sulphuric acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadisp[5.1.11.2]-heneicosan-21-one, polymer	SML = 5 mg/kg
92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	SML = 6 mg/kg
94960	000077-99-6	1,1,1-Trimethylpropane	SML = 6 mg/kg
95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0,6 mg/kg (8) (expressed as lithium)
95855	007732-18-5	Water	In compliance with Directive 98/83/EC
95859	—	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
95883	—	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V

Appendix 2

List of additives in Annex III to Directive 90/128/EEC for which the content of column "CAS No" is modified

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
39890	087826-41-3 069158-41-4 054686-97-4 081541-12-0	Bis(methylbenzylidene)sorbitol	
68125	037244-96-5	Nepheline syenite	

Appendix 3

List of additives in Annex III to Directive 90/128/EEC deleted

PM/REF No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
76720	009016-00-6 063148-62-9	Polydimethylsiloxane'	

ANNEX III

The following Annexes IV, V and VI are added:

'ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
18888	80181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	SML = 0,05 mg/kg for crotonic acid (as impurity) and in compliance with the specifications laid down in Annex IV.

ANNEX V

SPECIFICATIONS

Part A: General specifications

(to be fixed later)

Part B: Other specifications

PM/Ref No	Other specifications
18888	<p>3-HYDROXYBUTANOIC ACID-3-HYDROXYPENTANOIC ACID, COPOLYMER</p> <p><i>Definition</i> These 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 wild-type 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.</p> <p>— Chemical name Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)</p> <p>— CAS No 80181-31-3</p> <p>— Structural formula</p> $\begin{array}{c} \text{CH}_3 \\ \\ \text{CH}_2 \\ \\ \text{(-O-CH-CH}_2\text{-C-)}_m \end{array} - \begin{array}{c} \text{CH}_3 \\ \\ \text{CH}_2 \\ \\ \text{(O-CH-CH}_2\text{-C-)}_n \end{array}$ <p>where $n/(m+n)$ greater than 0 and less or equal to 0,25</p>

PM/Ref No	Other specifications
	<p>— Average molecular weight Not less than 150 000 daltons (measured by gel permeation chromatography).</p> <p>— Assay Not less than 98 % poly(3-D-hydroxybutanoato-co-3-D-hydroxypentanoato) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids.</p> <p><i>Description</i> White to off-white powder after isolation</p> <p><i>Characteristics</i></p> <p>— Identification tests:</p> <p>— Solubility Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.</p> <p>— Migration The migration of crotonic acid should not exceed 0,05 mg/kg food.</p> <p>— Purity Prior to granulation the raw material copolymer powder must contain:</p> <p>— Nitrogen Not more than 2 500 mg/kg of plastic</p> <p>— Zinc Not more than 100 mg/kg of plastic</p> <p>— Copper Not more than 5 mg/kg of plastic</p> <p>— Lead Not more than 2 mg/kg of plastic</p> <p>— Arsenic Not more than 1 mg/kg of plastic</p> <p>— Chromium Not more than 1 mg/kg of plastic.</p>
23547	POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (= 100 centistokes) at 25 °C
25385	TRIALLYLAMINE 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.
38320	4-(2-BENZOXAZOLYL)-4'-(5-METHYL-2-BENZOXAZOLYL) STILBENE Not more than 0,05 % w/w (quantity of substance used/quantity of the formulation)
76721	POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (=100 centistokes) at 25 °C
88640	SOYBEAN OIL, EPOXIDISED Oxirane < 8 %, iodine number < 6
95859	WAXES, REFINED, DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEED-STOCKS The product should have the following specifications: — Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w) — Viscosity not less than 11×10^{-6} m ² /s (= 11 centistokes) at 100 °C — Average molecular weight not less than 500
95883	WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS The product should have the following specifications: — Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w) — Viscosity not less than $8,5 \times 10^{-6}$ m ² /s (= 8,5 centistokes) at 100 °C — Average molecular weight not less than 480

ANNEX VI

NOTES RELATED TO THE COLUMN "RESTRICTIONS AND/OR SPECIFICATIONS"

- (1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 10060 and 23920.
- (3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 15760, 16990, 47680, 53650, 89440.
- (4) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 19540, 19960.
- (5) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 14200, 14230.
- (6) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 66560 and 66580.
- (7) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200, 92030.
- (8) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 85840 and 95725.
- (9) SML(T) = in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances:
 - (a) Badge (=2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether:
 - (b) Badge.H₂O.
 - (d) Badge.HCl.
 - (e) Badge.2HCl
 - (f) Badge.H₂O.HCl

However in aqueous food simulants, the SML(T) should also include Badge.2H₂O (c) unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five abovementioned substances (a)(b)(d)(e)(f) cannot exceed 1 mg/kg.

- (10) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the finished product does not comply with the second indent of Article 2 of Directive 89/109/EEC.'
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