

COMMISSION DIRECTIVE 2004/19/EC
of 1 March 2004

amending Directive 2002/72/EC 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 European Food Safety Authority,

Whereas:

- (1) Commission Directive 2002/72/EC ⁽²⁾ sets out rules for plastic materials and articles which are intended to come into contact with foodstuffs.
- (2) Directive 2002/72/EC establishes a list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. On the basis of new information, certain monomers provisionally admitted at national level as well as new monomers should be included in the Community list of permitted substances in that Directive.
- (3) Directive 2002/72/EC also contains an incomplete list of additives which may be used in the manufacture of plastic materials and articles. That list should be amended so as to include other additives evaluated by the European Food Safety Authority (the Authority).
- (4) For certain substances, the restrictions already established at Community level should be amended on the basis of the new information available.
- (5) The current list of additives is incomplete inasmuch as it does not contain all substances currently accepted in one or more Member States. Those additives continue to be regulated by national laws pending a decision on inclusion into the Community list.
- (6) The current list of additives should become a positive list in order to harmonise the use of these additives in the Community. For additives which are already placed on the market in one or more of the Member States, sufficient time should be allowed for the submission of the data necessary for the Authority to carry out an evaluation of their safety. Therefore, the deadline for the submission of the data should be set as 31 December 2006.
- (7) If the data are in compliance with the Authority requirements, it should be possible to continue to use those additives in accordance with national law until their evaluation is completed. If the data are not in compliance with the Authority requirements or are submitted later than 31 December 2006 those additives should not be included in the first positive list.
- (8) The date when the list of additives is to become a positive list should be established no later than 31 December 2007 as it is impossible to know the number of additives for which the data required by the Authority will be supplied. That date should be fixed taking into account the time needed for the Authority to evaluate all the applications supplied on time.
- (9) Some substances used to manufacture plastic materials and articles intended to come into contact with food are also added directly to foodstuffs. These substances should not migrate from the materials or articles into the foodstuffs in quantities that could exceed the limits set in the relevant food legislation or in this Directive whichever provides the lower restriction. In any case, these substances should not migrate from the materials or articles into the foodstuffs in quantities having a technological function in the final food. The users of materials and articles which may release these substances into foodstuffs should be appropriately informed in order to be able to comply with other relevant food legislation.
- (10) Member States should retain the right to lay down rules concerning substances used as active components in active food contact materials and articles until Community provisions are adopted.
- (11) Directive 2002/72/EC should therefore be amended accordingly.

⁽¹⁾ OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 220, 15.8.2002, p. 18. Directive as amended by Directive 2004/1/EC (OJ L 7, 13.1.2004, p. 45).

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

- adhesives and adhesion promoters,
- printing inks;

(b) colorants;

(c) solvents.'

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/72/EC is amended as follows:

1. In Article 3, paragraphs 1 and 2 are replaced by the following:

'1. Only those monomers and other starting substances listed in Annex II, section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

2. By way of derogation from paragraph 1, the monomers and other starting substances listed in Annex II, section B may continue to be used until 31 December 2004 at the latest, pending their evaluation by the European Food Safety Authority (hereinafter referred to as the Authority).'

2. Article 4 is replaced by the following:

'Article 4

1. A list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III.

That list of additives shall be considered to be an incomplete list until the Commission decides, in accordance with Article 4a, that it shall become a positive Community list of authorised additives, to the exclusion of all others.

The Commission shall establish, by 31 December 2007 at the latest, the date when that list shall become a positive list.

2. For the additives listed in Annex III, section B, the verification of compliance with the specific migration limits in simulants D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC and Article 1 of Directive 85/572/EEC shall apply from 1 July 2006.

3. The lists in Annex III, sections A and B do not yet include the following additives:

(a) additives used only in the manufacture of:

- surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,
- epoxy resins,

3. The following Articles 4a and 4b are inserted:

'Article 4a

1. A new additive may always be added to the list of substances referred to in Article 4(1) following an evaluation of its safety by the Authority.

2. Member States shall provide that any person interested in the inclusion in the list referred to in Article 4(1) of an additive, which is already placed on the market in one or more of the Member States, shall submit data for the evaluation of its safety by the Authority by 31 December 2006 at the latest.

For the submission of the required data, the applicant shall consult the "Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation".

3. If during the examination of the data referred to in paragraph 2, the Authority calls for supplementary information, the additive may continue to be used subject to national law until the Authority has issued an opinion, provided that the information is submitted within the time limits specified by the Authority.

4. The Commission shall establish, by 31 December 2007 at the latest, a provisional list of additives which may continue to be used after 31 December 2007 subject to national law until the Authority has evaluated them.

5. The inclusion of an additive in the provisional list is subject to the following conditions:

- (a) the additive must be permitted in one or more of the Member States no later than 31 December 2006;
- (b) the data referred to in paragraph 2 concerning that additive must have been supplied in accordance with the Authority requirements no later than 31 December 2006.

Article 4b

Without prejudice to Article 4 of Directive 89/109/EEC, Member States may not authorise after 31 December 2006 additives referred to in Article 4(1) which were never evaluated by the Scientific Committee on Food or the Authority.'

4. The following Article 5a is inserted:

'Article 5a

5. Additives referred to in Article 4, which are authorised as food additives by Council Directive 89/107/EEC (*) or flavourings by Council Directive 88/388/EEC (**) shall not migrate into:

- (a) foodstuffs in quantities having a technological function in the final foodstuffs;
- (b) foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in Article 4 of this Directive, whichever is the lower;
- (c) foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in Article 4 of this Directive.

2. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 1 shall be accompanied by a written declaration containing the information referred to in Article 9(1)(b).

3. By way of derogation from paragraph 1, when the substances referred to in point (a) of paragraph 1 are used as active components of active food contact materials and articles, they may be subject to national provisions pending the adoption of Community provisions.

(*) OJ L 40, 11.2.1989, p. 27.

(**) OJ L 184, 15.7.1988, p. 61.'

5. Article 7 is replaced by the following:

'Article 7

The specific migration limits in the list set out in Annexes II and III are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:

- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
- (b) sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in Annexes II and III, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².'

6. In Article 8, paragraph 2 is replaced by the following:

'2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if the value of overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.'

7. Article 9 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration, which shall:

- (a) be in accordance with Article 6(5) of Directive 89/109/EEC;
- (b) provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC (*), 95/45/EC (**) and 2002/82/EC (***) to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

(*) OJ L 178, 28.7.1995, p. 1.

(**) OJ L 226, 22.9.1995, p. 1.

(***) OJ L 292, 28.10.2002, p. 1.;

(b) paragraph 2 is deleted.

8. Annexes II to VI are amended in accordance with Annexes I to V to this Directive.

Article 2

1. Member States shall adopt and publish, by 1 September 2005 at the latest, the provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

- (a) permit the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive, from 1 September 2005;
- (b) prohibit 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, from 1 March 2006.

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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 1 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

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

1. in point 8, the definition of QM is replaced by the following:

'QM = Maximum permitted quantity of the "residual" substance in the material or article. For the purpose of this Directive the quantity of the substance in the material or article shall be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;'

2. the following monomers and other starting substances are inserted, in the appropriate numerical order, in the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'13323	000102-40-9	1,3-Bis(2-hydroxyethoxy)benzene	SML = 0,05 mg/kg
16540	000102-09-0	Diphenyl carbonate	SML = 0,05 mg/kg
18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0,05 mg/kg
20440	000097-90-5	Methacrylic acid, diester with ethylene-glycol	SML = 0,05 mg/kg
22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ⁽²⁹⁾
23070	000102-39-6	(1,3-Phenylenedioxy)diacetic acid	QMA = 0,05 mg/6 dm ²

3. for the following monomers and other starting substances listed in the table in section A, the content of the columns 'Name' or 'CAS No' or 'Restrictions and/or specifications' is replaced by the following:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0,05 mg/6 dm ² for the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Annex V
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0,6 mg/kg ⁽²⁸⁾
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO) ⁽²⁶⁾
18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	SML = 0,05 mg/kg
22150	000691-37-2	4-Methyl-1-pentene	SML = 0,05 mg/kg
22331	025513-64-8	Mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²
22332	—	Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
24190	065997-05-9	Rosin wood'	

4. the following monomers and other starting substances are deleted from the table in section B and inserted, in the appropriate numerical order, in the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'10599/90A	061788-89-4	Acids, fatty, unsaturated (C ₁₈), dimers, distilled	QMA(T) = 0,05 mg/6 dm ² (27)
10599/91	061788-89-4	Acids, fatty, unsaturated (C ₁₈), dimers, non distilled	QMA(T) = 0,05 mg/6 dm ² (27)
10599/92A	068783-41-5	Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled	QMA(T) = 0,05 mg/6 dm ² (27)
10599/93	068783-41-5	Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, non distilled	QMA(T) = 0,05 mg/6 dm ² (27)
14800	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm ² (33)
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0,05 mg/kg (32). To be used only in polyamides.
17110	016219-75-3	5-Ethylidenebicyclo[2,2,1]hept-2-ene	QMA = 0,05 mg/6 dm ² . The ratio surface/quantity of food shall be lower than 2 dm ² /kg
18700	000629-11-8	1,6-Hexanediol	SML = 0,05 mg/kg
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	QMA = 0,05 mg/6 dm ²

5. The following monomers and other starting substances are deleted from the table in Section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA = 5 mg/6 dm ²
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²

ANNEX II

Annex III is amended as follows:

1. point 1 is replaced by the following:

'1. This Annex contains the list of:

- (a) substances which are incorporated into plastics to achieve a technical effect in the finished product, including "polymeric additives". They are intended to be present in the finished articles;
- (b) substances used to provide a suitable medium in which polymerisation occurs.

For the purposes of this Annex, the substances referred to in (a) and (b) are hereinafter referred to as "additives".

For the purpose of this Annex, "Polymeric additives" means any polymer and/or prepolymer and/or oligomer which may be added to plastics in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerisation occurs.

The list does not include:

- (a) the substances which directly influence the formation of polymers;
- (b) colorants;
- (c) solvents.;

2. section A is amended as follows:

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

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34850	143925-92-2	Amines, bis(hydrogenated tallow alkyl) oxidised	QM = For use only: (a) in polyolefines at 0,1 % (w/w) but not in LDPE when it is in contact with foods for which the Directive 85/572/EEC establishes a reduction factor less than 3; (b) in PET at 0,25 % (w/w) in contact with foods other of those for which the simulant D is laid down in Directive 85/572/EEC 85/572/EEC
34895	000088-68-6	2-Aminobenzamide	SML = 0,05 mg/kg. To be used only for PET for water and beverages
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0,6 mg/kg ⁽²⁸⁾
42880	008001-79-4	Castor oil	
45600	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm ² ⁽³³⁾
45640	005232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	SML = 0,05 mg/kg
46700	—	5,7-di-tert-Butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	SML = 5 mg/kg

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm ²
56535	—	Glycerol, esters with nonanoic acid	
59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg ⁽²²⁾ (expressed as Formaldehyde)
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0,05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.
69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ⁽²⁹⁾
76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol	SML = 30 mg/kg
85601	—	Silicates, natural (with the exception of asbestos)	
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer'	

(b) for the following additives of section A, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg
77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether	SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V'

(c) the following additives are deleted from the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'56565	—	Glycerol, esters with nonanoic acid	
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
76865	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C ₁₀ -C ₁₈ or n-octanol and/or n-decanol	SML = 30 mg/kg
85600	—	Silicates, natural'	

3. section B is amended as follows:

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

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butylphenyl) phosphate	SML = 5 mg/kg
38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	SML = 30 mg/kg
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	SML = 3,0 mg/kg
54880	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg ⁽²²⁾
55200	001166-52-5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg ⁽³⁴⁾
55280	001034-01-1	Gallic acid, octyl ester	SML(T) = 30 mg/kg ⁽³⁴⁾
55360	000121-79-9	Gallic acid, propyl ester	SML(T) = 30 mg/kg ⁽³⁴⁾
67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0,05 mg/kg ⁽³¹⁾
76680	068132-00-3	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg ⁽¹⁾
86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂)
86920	007632-00-0	Sodium nitrite	SML = 0,6 mg/kg
86960	007757-83-7	Sodium sulphite	SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂)
87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂)
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg'

(b) the following additives are deleted from the table in section B:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm ²
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0,05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer'	

ANNEX III

Annex IV is replaced by the following:

'ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer	In compliance with specifications included in Annex V'

ANNEX IV

In Annex V the previous specifications in part B for reference No 16690 and 18888 are replaced by the following and new specifications are added for reference No 11530 and 77895

Reference No	OTHER SPECIFICATIONS
11530	Acrylic acid, 2-hydroxypropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 002918-23-2)
16690	Divinylbenzene It may contain up to 45 % (m/m) of Ethylvinylbenzene
18888	<p>3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer</p> <p>Definition The 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 HI6 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 number 080181-31-3</p> <p>Structural formula</p> $ \begin{array}{cccc} & & \text{CH}_3 & \\ & & & \\ \text{CH}_3 & \text{O} & \text{CH}_2 & \text{O} \\ & & & \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & (\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n & \\ \text{where } n/(m+n) \text{ greater than } 0 \text{ and less or equal to } 0,25 \end{array} $ <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-hydroxybutanoate-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids</p> <p>Description White to off-white powder after isolation</p> <p>Characteristics</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>Restriction QMA for crotonic acid is 0.05 mg/6 dm²</p> <p>Purity Prior to granulation the raw material copolymer powder must contain:</p> <ul style="list-style-type: none"> — nitrogen Not more than 2 500 mg/kg of plastic — zinc Not more than 100 mg/kg of plastic — copper Not more than 5 mg/kg of plastic — lead Not more than 2 mg/kg of plastic — arsenic Not more than 1 mg/kg of plastic — chromium Not more than 1 mg/kg of plastic

Reference No	OTHER SPECIFICATIONS
77895	Polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether (approximately 28 %) — fatty alcohols (C ₁₆ -C ₁₈) (approximately 48 %) — ethyleneglycol monoalkyl (C ₁₆ -C ₁₈) ether (approximately 24 %)

ANNEX V

Annex VI is replaced by the following:

'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 reference 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 reference Nos: 15760, 16990, 47680, 53650 and 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 reference Nos: 19540, 19960 and 64800.
- (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 reference Nos: 14200, 14230 and 41840.
- (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 reference 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 levels of the following substances mentioned as reference Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
- (⁸) 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 mentioned as reference Nos: 38000, 42400, 64320, 67896, 73040, 85760, 85840, 85920 and 95725.
- (⁹) 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.
- (¹⁰) 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 mentioned as reference Nos: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.
- (¹¹) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels (expressed as Iodine) of the following substances mentioned as reference Nos: 45200, 64320, 81680 and 86800.
- (¹²) 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 mentioned as reference Nos: 36720, 36800, 36840 and 92000.
- (¹³) 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 mentioned as reference Nos: 39090 and 39120.
- (¹⁴) 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 mentioned as reference Nos: 44960, 68078, 82020 and 89170.
- (¹⁵) 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 mentioned as reference Nos: 15970, 48640, 48720, 48880, 61280, 61360 and 61600.
- (¹⁶) 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 mentioned as reference Nos: 49600, 67520 and 83599.
- (¹⁷) 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 mentioned as reference Nos: 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.
- (¹⁸) 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 mentioned as reference Nos: 67600, 67680 and 67760.
- (¹⁹) 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 mentioned as reference Nos: 60400, 60480 and 61440.
- (²⁰) 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 mentioned as reference Nos: 66400 and 66480.
- (²¹) 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 mentioned as reference Nos: 93120 and 93280.

- (²²) 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 mentioned as reference Nos: 17260, 18670, 54880 and 59280.
- (²³) 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 mentioned as reference Nos: 13620, 36840, 40320 and 87040.
- (²⁴) 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 mentioned as reference Nos: 13720 and 40580.
- (²⁵) 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 mentioned as reference Nos: 16650 and 51570.
- (²⁶) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.
- (²⁷) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 10599/90A, 10599/91, 10599/92A and 10599/93.
- (²⁸) 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 mentioned as reference Nos: 13480 and 39680.
- (²⁹) 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 mentioned as reference Nos: 22775 and 69920.
- (³⁰) 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 mentioned as reference Nos: 86480, 86960 and 87120.
- (³¹) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.
- (³²) Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D (unstable).
- (³³) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14800 and 45600.
- (³⁴) 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 mentioned as reference Nos: 55200, 55280 and 55360.'
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