

2005 No. 49

FOOD

**The Plastic Materials and Articles in Contact with Food
(Amendment) Regulations (Northern Ireland) 2005**

Made - - - - - *24th February 2005*

Coming into operation *18th March 2005*

The Department of Health, Social Services and Public Safety(a), in exercise of the powers conferred on it by Articles 15(2), 16(1), 25(1)(a) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(b) and of all other powers enabling it in that behalf, having had regard, in accordance with Article 47(3A) of the said Order, to relevant advice given by the Food Standards Agency, and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2005, and shall come into operation on 18th March 2005.

Amendments to the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998

2. The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998(d) shall be amended, in accordance with regulations 3 to 16.

3. In regulation 2 (interpretation) –

(a) in paragraph (1) –

(i) for the definition of “additive” there shall be substituted “ “additive” means a substance as defined in paragraph 1 of the general introduction to Annex III to the Directive as read with paragraph 3 of Article 4 of the Directive;”;

(ii) in the definition of “Council Directive 82/711”, omit “as amended” to the end;

(iii) after the definition of “Council Directive 82/711” there shall be inserted –

“ “Council Directive 88/388” means Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production(e);

(a) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.) Article 3

(b) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1663 (N.I.12) and paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c. 28 and S.R. 2004 No. 482

(c) O.J. No. L31, 1.2.2002, p. 1

(d) S.R. 1998 No. 264 as amended by S.R. 2000 No. 402, S.R. 2002 No. 316 and S.R. 2003 No. 2

(e) O.J. No. L184, 15.7.88, p. 61

“Council Directive 89/107” means Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption(a);”;

- (iv) omit the definition of “EEA Agreement”;
- (v) for the definition of “EEA State” there shall be substituted “ “EEA State” means a Member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;”;
- (vi) immediately after the definition of “EEA State” there shall be inserted –
 - “ “EFSA” means the European Food Safety Authority;”;
 - (i) immediately after the definition of “preparation” there shall be inserted –
 - “ “the purity Directives” means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(b), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(c) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(d);”;
- (b) after paragraph (5) there shall be added –

“(6) Any reference in these Regulations to a Community instrument shall be construed as a reference to that instrument as amended at the time the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2005 were made.”.

4. In Regulation 4 (restriction on the use of monomers in the manufacture of plastic materials and articles) –

- (a) in paragraph (2) omit sub-paragraphs (a) and (b);
- (b) in paragraph (5)(b)(ii) after “material” in each case insert “or article”.

5. In regulation 5 (restriction on the use of additives in the manufacture of plastic materials and articles) –

- (a) in paragraph (1) add after sub-paragraph (d) –
 - “(e) any food additive authorised by Council Directive 89/107 or any flavouring authorised by Council Directive 88/388 that migrates into food –
 - (i) in a quantity that has a technological function in the final food product, or
 - (ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for in Council Directive 89/107 or Council Directive 88/388 as appropriate, or in Schedule 2 to these Regulations, whichever is the lower.”.
- (b) in paragraph (4)(b)(ii) after “material” in each case insert “or article”.

6. After regulation 5A there shall be inserted –

“5B. Applications for inclusion of an additive in the Community list of authorised additives

(1) This regulation applies to any person who wishes to make an application for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive.

(2) An application mentioned in paragraph (1) including supporting data must be made to EFSA before 1st January 2007.

(3) If, during examination of the data referred to in paragraph (2), EFSA calls for supplementary information, the eligible additive may, if permitted to be used under Northern

(a) O.J. No. L40, 11.2.89, p. 27
(b) O.J. No. L178, 28.7.95, p. 1
(c) O.J. No. L226, 22.9.95, p. 1
(d) O.J. No. L339, 30.12.96, p. 1

Ireland law, continue to be so used until EFSA has issued an opinion, provided such information is submitted within the time limits specified by EFSA.

(4) For the purposes of this regulation an eligible additive is one whose use is permitted in one or more Member States before 1st January 2007.”.

7. For regulation 8 (labelling) there shall be substituted –

“At marketing stages other than the retail stage a person who is in possession of any plastic material or article intended to come into contact with food shall ensure that the plastic material or article is accompanied by a written declaration which –

- (a) attests that it complies with the legislation applicable to it; and
- (b) provides, in respect of substances that are subject to a restriction on quantities migrating into food, information obtained from experimental data or theoretical calculation concerning –
 - (i) the levels of migration specific to those substances;
 - (ii) where appropriate, purity criteria in accordance with the purity Directives.”.

8. In regulation 10 (offences) –

(a) in paragraph (1) for “8(1)” there shall be substituted “8”;

(b) after paragraph (24) there shall be added –

“(25) In any proceedings for an offence under these Regulations it shall be a defence to prove that –

- (a) the act constituting the offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st March 2006; and
- (b) the act constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2005 had not been in force at the time that act occurred.”.

9. In Schedule 1, Part I –

(a) in Section A (monomers authorised without time limit) –

- (i) there shall be inserted in the appropriate numerical order the entries set out in Schedule 1;
- (ii) for items 15A, 39, 70, 120B, 147, 147A, 147B and 188 there shall be substituted the entries set out in Schedule 2;
- (iii) items 76B and 76C with their corresponding entries shall be omitted;

(b) omit Sections B and C.

10. In Schedule 1, Part II (supplementary) paragraph 4,

(a) at the end of note (21) for “and 18670,” substitute “19670, 54880 and 59280.”;

(b) after note (25) there shall be added –

“(27) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

(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 case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.”.

11. In Schedule 2, Part I (incomplete list of additives used in the manufacture of plastic materials and articles) –

- (a) there shall be inserted in appropriate numerical order the entries set out in Schedule 3;
- (b) for items 60A and 198A there shall be substituted the entries set out in Schedule 4;
- (c) items 112, 173A, 195C and 240 with their corresponding entries shall be omitted.

12. In Schedule 2, Part II (incomplete list of additives used in the manufacture of plastic materials and articles to which paragraph 5 of Part III of Schedule 2 applies) –

- (a) there shall be inserted in appropriate numerical order the entries set out in Schedule 5;
- (b) items 28, 80 and 111A with their corresponding entries shall be omitted.

13. In Schedule 2, Part III (supplementary) –

(a) in paragraph 4 –

- (i) in note (8), there shall be inserted in the appropriate numerical order “38000” and “67896”;
- (ii) in note (10), after “levels” insert “(expressed as iodine)”;
- (iii) at the end of note (21), for “and 18670,” substitute “, 18670, 54880 and 59280”;
- (iv) after note (24) add –

“(26) QMA(T) in this 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 case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

(30) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF 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 isoctane as substitute of stimulant D (unstable).

(33) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.

(34) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 55200, 55280 and 55360.”;

(b) in paragraph 5 for “1st January 2004” there shall be substituted “1st July 2006”.

14. In Schedule 2A (products obtained by bacterial fermentation) for the entry in the column headed “restrictions and specifications” there shall be substituted –

“In compliance with specifications included in Schedule 2B”.

15. For Schedule 2B (specifications) there shall be substituted the Table set out in Schedule 6.

16. For paragraph 4(b) of Part I (basic rules) of Schedule 4 (overall and specific migration testing using food simulants) there shall be substituted –

“(b) omit the migration, the substitute or the alternative tests where –

- (i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or
- (ii) the conditions for non-compulsory testing set out in Article 8.2 and 8.3 of the Directive are met.”.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 24th February 2005.

(L.S.)

Deirdre Kenny

A senior officer of the Department of Health, Social Services and Public Safety

SCHEDULE 1

Regulation 9(a)(i)

(ENTRIES TO BE INSERTED IN SECTION A OF PART I OF SCHEDULE 1)

| <i>Item</i> | 1 <i>PM/REF No.</i> | 2 <i>CAS No.</i> | 3 <i>Name</i> | 4 <i>Restrictions and specifications</i> |
|-------------|------------------------|---------------------|---|--|
| 6A | 10599/90A | 061788-89-4 | Acids, fatty, unsaturated (C ₁₈), dimers, distilled | QMA(T) = 0.05 mg/6 dm ² ⁽²⁷⁾ |
| 6B | 10599/91 | 061788-89-4 | Acids, fatty, unsaturated (C ₁₈), dimers, non-distilled | QMA(T) = 0.05 mg/6 dm ² ⁽²⁷⁾ |
| 6C | 10599/92A | 068783-41-5 | Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled | QMA(T) = 0.05 mg/6 dm ² ⁽²⁷⁾ |
| 6D | 10599/93 | 068783-41-5 | Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, non-distilled | QMA(T) = 0.05 mg/6 dm ² ⁽²⁷⁾ |
| 37A | 13323 | 000102-40-9 | 1,3-Bis(2-hydroxyethoxy) benzene | SML = 0.05 mg/kg |
| 68MA | 14800 | 003724-65-0 | Crotonic acid | QMA(T) = 0.05 mg/6 dm ² ⁽³³⁾ |
| 87A | 16210 | 006864-37-5 | 3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane | SML = 0.05 mg/kg ⁽³²⁾ . To be used only in polyamides. |
| 89A | 16540 | 000102-09-0 | Diphenyl carbonate | SML = 0.05 mg/kg |
| 101A | 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 |
| 118MA | 18700 | 000629-11-8 | 1,6-Hexanediol | SML = 0.05 mg/kg |
| 120ZA | 18896 | 001679-51-2 | 4-(Hydroxymethyl)-1-cyclohexene | SML = 0.05 mg/kg |
| 135BM | 20440 | 000097-90-5 | Methacrylic acid, diester with ethyleneglyco | SML = 0.05 mg/kg |
| 142A | 21400 | 054276-35-6 | Methacrylic acid, sulphopropyl ester | QMA = 0.05 mg/6 dm ² |
| 156XA | 22775 | 000144-62-7 | Oxalic acid | SML(T) = 6 mg/kg ⁽²⁹⁾ |
| 161A | 23070 | 000102-39-6 | (1,3-Phenylenedioxy) diacetic acid | QMA = 0.05 mg/6 dm ² |

SCHEDULE 2

Regulation 9(a)(ii)

(ENTRIES TO BE SUBSTITUTED FOR ENTRIES IN SECTION A OF PART I OF SCHEDULE 1)

| <i>Item</i> | 1 <i>PM/REF No.</i> | 2 <i>CAS No.</i> | 3 <i>Name</i> | 4 <i>Restrictions and specifications</i> |
|-------------|------------------------|---------------------|--|--|
| 15A | 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 Schedule 2B |
| 39 | 13480 | 000080-05-7 | 2,2-Bis(4-hydroxyphenyl) propane | SML(T) = 0.6 mg/kg ⁽²⁸⁾ |
| 70 | 14950 | 003173-53-3 | Cyclohexyl isocyanate | QMT(T) = 1 mg/kg in FP (expressed as NCO) ⁽²⁶⁾ |
| 120B | 18898 | 000103-90-2 | N-(4-Hydroxyphenyl) acetamide | SML = 0.05 mg/kg |
| 147 | 22150 | 000691-37-2 | 4-Methyl-1-pentene | SML = 0.05 mg/kg |
| 147A | 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 |
| 147B | 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⁾ |
| 188 | 24190 | 065997-05-9 | Rosin Wood | |

SCHEDULE 3

Regulation 11(a)

(ENTRIES TO BE INSERTED IN PART I OF SCHEDULE 2)

| Item | 1 PM/REF No. | 2 CAS No. | 3 Name | 4 Restrictions and specifications |
|------|-----------------|--------------|--|---|
| 18A | 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 than those for which the simulant D is laid down in Directive 85/572/EEC |
| 18B | 34895 | 000088-68-6 | 2-Aminobenzamide | SML = 0.05 mg/kg. To be used only for PET for water and beverages |
| 37AA | 39680 | 000080-05-7 | 2,2-Bis(4-hydroxyphenyl) propane | SML(T) = 0.6 mg/kg ⁽²⁸⁾ |
| 51A | 42880 | 008001-79-4 | Castor oil | |
| 61A | 45600 | 003724-65-0 | Crotonic acid | QMA(T) = 0.05 mg/6 dm ² ⁽³³⁾ |
| 61B | 45640 | 005232-99-5 | 2-Cyano-3,3 diphenylacrylic acid, ethyl ester | SML = 0.05 mg/kg |
| 69A | 46700 | – | 5,7-di-tert-butyl-3-(3,4-and 2,3-di-methylphenyl)-3H-benzofuran-2-one containing: (a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl) 3H-benzofuran-2-one (80-100% w/w); and (b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0-20% w/w) | SML = 5 mg/kg |
| 69B | 46720 | 004130-42-1 | 2,6-Di-tert-butyl-4-ethylphenol | QMA = 4.8 mg/6 dm ² |
| 109A | 56535 | – | Glycerol, esters with nonanoic acid | |
| 131A | 59280 | 000100-97-0 | Hexamethylenetetramine | SML(T) = 15 mg/kg ⁽²¹⁾ (expressed as Formaldehyde) |
| 178A | 68078 | 027253-31-2 | Neodecanoic acid, cobalt salt | SML(T) = 0.05 mg/kg (expressed as |

| <i>Item</i> | 1 <i>PM/REF No.</i> | 2 <i>CAS No.</i> | 3 <i>Name</i> | 4 <i>Restrictions and specifications</i> |
|-------------|------------------------|---------------------|---|---|
| | | | | Neodecanoic acid) and SML(T) = 0.05 mg/kg (¹³) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC |
| 182A | 69920 | 000144-62-7 | Oxalic acid | SML(T) = 6 mg/kg (²⁹) |
| 195D | 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 |
| 240ZA | 85601 | – | Silicates, natural (with the exception of asbestos) | |
| 280B | 95000 | 028931-67-1 | Trimethylolpropane trimethacrylatemethyl methacrylate copolymer | |

SCHEDULE 4

Regulation 11(b)

(ENTRIES TO BE SUBSTITUTED FOR THE ENTRIES IN PART I OF SCHEDULE 2)

| <i>Item</i> | 1 <i>PM/REF No.</i> | 2 <i>CAS No.</i> | 3 <i>Name</i> | 4 <i>Restrictions and specifications</i> |
|-------------|------------------------|---------------------|---|---|
| 60A | 45450 | 068610-51-5 | p-Cresol-dicyclopentadiene isobutylene, copolymer | SML = 5 mg/kg |
| 198A | 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 Schedule 2B |

SCHEDULE 5

Regulation 12(a)

(ENTRIES TO BE INSERTED IN PART II OF SCHEDULE 2)

| 1 | 2 | 3 | 4 | |
|-------------|-------------------|----------------|---|--|
| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i> | <i>Restrictions and specifications</i> |
| 4A | 34650 | 151841-65-5 | Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate | SML = 5 mg/kg |
| 7A | 38000 | 000553-54-8 | Benzoic acid, lithium salt | SML(T) = 0.6 mg/kg (8) (expressed as Lithium) |
| 18A | 40720 | 025013-16-5 | tert-Butyl-4-hydroxyanisole (= BHA) | SML = 30 mg/kg |
| 27B | 46640 | 000128-37-0 | 2,6-Di-tert-butyl-p-cresol (= BHT) | SML = 3.0 mg/kg |
| 54A | 54880 | 000050-00-0 | Formaldehyde | SML(T) = 15 mg/kg ⁽²¹⁾ |
| 54B | 55200 | 001166-52-5 | Gallic acid, dodecyl ester | SML(T) = 30 mg/kg ⁽³⁴⁾ |
| 54C | 55280 | 001034-01-1 | Gallic acid, octyl ester | SML(T) = 30 mg/kg ⁽³⁴⁾ |
| 54D | 55360 | 000121-79-9 | Gallic acid, propyl ester | SML(T) = 30 mg/kg ⁽³⁴⁾ |
| 79A | 67896 | 020336-96-3 | Myristic acid, lithium salt | SML(T) = 0.6 mg/kg (8) (expressed as Lithium) |
| 83A | 71935 | 007601-89-0 | Perchloric acid, sodium salt monohydrate | SML 0.05 mg/kg ⁽³¹⁾ |
| 88A | 76680 | 068132-00-3 | Polycyclopentadiene, hydrogenated | SML = 5 mg/kg ⁽¹⁾ |
| 100A | 86480 | 007631-90-5 | Sodium bisulphite | SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂) |
| 102A | 86920 | 007632-00-0 | Sodium nitrite | SML = 0.6 mg/kg |
| 102B | 86960 | 007757-83-7 | Sodium sulphite | SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂) |
| 102C | 87120 | 007772-98-7 | Sodium thiosulphate | SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as SO ₂) |
| 110A | 94400 | 036443-68-2 | Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate] | SML = 9 mg/kg |

SCHEDULE 6

Regulation 15

(ENTRIES TO BE SUBSTITUTED FOR SCHEDULE 2B)

| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i> |
|-------------|-------------------|--|
| 1 | 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) |
| 2 | 16690 | Divinylbenzene It may contain up to 45% (m/m) of Ethylvinylbenzene |
| 3 | 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 H16 NCIMB 10422. 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}{ccccccc} & & & & \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: Solubility Soluble in chlorinated hydrocarbons such as a 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> |

| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i> |
|-------------|-------------------|--|
| | | Purity — 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 |
| 4 | 23547 | Polydimethylsiloxane (MW > 6800) Minimum viscosity $100 \times 10^{-6} \text{ m}^2/\text{s}$ centistokes at 25°C |
| 5 | 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. |
| 6 | 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) |
| 7 | 43680 | Chlorodifluoromethane Content of chlorofluoromethane less than 1 mg/kg of the substance |
| 8 | 47210 | Dibutylthiostannoic acid polymer Molecular unit = $(\text{C}_8\text{H}_{18}\text{S}_3\text{Sn}_2)_n$ ($n = 1, 5-2$) |
| 9 | 76721 | Polydimethylsiloxane (Mw > 6800) Minimum viscosity $100 \times 10^{-6} \text{ m}^2/\text{s}$ (= 100 centistokes) at 25°C |
| 10 | 77895 | Polyethyleneglycol (EO = 2-6) monoalkyl ($\text{C}_{16}\text{-C}_{18}$) ether The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6) monoalkyl ($\text{C}_{16}\text{-C}_{18}$) ether (approximately 28%) — fatty alcohols ($\text{C}_{16}\text{-C}_{18}$) (approximately 48%) — ethyleneglycol monoalkyl ($\text{C}_{16}\text{-C}_{18}$) ether (approximately 24%) |
| 11 | 83595 | Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl Composition — 4,4'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 38613-77-3) (36-46% w/w ⁽¹⁾) — 4,3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 118421-00-4) (17-23% w/w) — 3,3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 118421-01-5) (1-5% w/w ⁽¹⁾) — 4-Biphenylene-0,0-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 91362-37-7) (11-19% w/w ⁽¹⁾) — Tris (2,4-di-tert-butylphenyl) phosphite (CAS No. 31570-04-4) (9-18% w/w ⁽¹⁾) — 4,4'-Biphenylene-0,0-bis (2,4-di-tert-butylphenyl) phosphonate-0,0-bis (2,4-di-tert-butylphenyl) phosphonite (CAS No. 112949-970) (5% w/w ⁽¹⁾) |

| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i> |
|-------------|-------------------|--|
| | | <p>Other specifications</p> <ul style="list-style-type: none"> — Phosphor content of minimum 5.4% to 5.9% — Acid value of maximum 10 mg KOH per gram — Melt range of 85-110°C |
| 12 | 88640 | <p>Soybean oil, epoxidized</p> <p>Oxirane < 8%, iodine number < 6</p> |
| 13 | 95859 | <p>Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks</p> <p>The product shall have the following specifications:</p> <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than $11 \times 10^{-6} \text{ m}^2/\text{s}$ (= 11 centistokes) at 100°C — Average molecular weight not less than 500 |
| 14 | 95883 | <p>White mineral oils, paraffinic, derived from petroleum hydrocarbon feedstocks</p> <p>The product shall have the following specifications:</p> <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than $8.5 \times 10^{-6} \text{ m}^2/\text{s}$ (= 8.5 centistokes) at 100°C — Average molecular weight not less than 480 |

EXPLANATORY NOTE

(This note is not part of the Regulations).

1. These Regulations, further amend the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998 (S.R. 1998 No.264, “the 1998 Regulations”). These Regulations implement Commission Directive 2004/19/EC amending Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L220, 15.8.2002, p. 18), (“the Directive”).

2. The Regulations amend the main body of the 1998 Regulations by –

- (a) amending the definition of “additive” to maintain consistency with the Directive (*regulation 3(a)(i)*);
- (b) removing references to lists of substances whose authorisations are now spent (*regulation 4(a)*);
- (c) extending to articles the provisions of regulation 4(5) of the 1998 Regulations that formerly only applied to materials (*regulation 4(b)*);
- (d) adding a restriction on the use of additives in the manufacture of plastic materials and articles which relates to substances also used as food additives or flavourings (*regulation 5(a)*);
- (e) extending to articles the provisions of regulation 5(4) of the 1998 Regulations that formerly only applied to materials (*regulations 5(b)*);
- (f) making provision for the procedure to be followed and the time limits to be observed by any person wishing to have an additive included in the Community list of authorised additives (*regulation 6*);
- (g) amending the labelling requirements for plastic materials and articles at the pre-retail stage so as to require additional information to be given (*regulation 7*);
- (h) making a consequential amendment to regulation 10 (offences) brought about by the amendment to the labelling requirements (*regulation 8(a)*);
- (i) providing a defence to breach the 1998 Regulations as last amended by these Regulations in respect of plastic materials or articles manufactured or imported into the European Community before 1st March 2006 (*regulation 8(b)*).

3. They also amend the Schedules to the 1998 Regulations by –

- (a) inserting new entries, and amending or deleting some existing ones, in the list of monomers authorised without time limit in Section A of Part I of Schedule 1 (*regulation 9(a) and Schedules 1 & 2*);
- (b) removing the lists of entries for monomers authorised with a time limit that has now expired (*regulation 9(b)*);
- (c) adding further supplementary specifications in Part II of Schedule 1 (*regulation 10*);
- (d) inserting new entries and amending or deleting some existing entries in the list of additives used in the manufacture of plastic materials articles in Part I of Schedule 2 (*regulation 11 and Schedules 3 & 4*);
- (e) inserting new entries and deleting some existing entries in the list of additives used in the manufacture of plastic materials and articles set out in Part II of Schedule 2 (*regulation 12 and Schedule 5*);
- (f) adding further supplementary specifications to Part III of Schedule 2, and extending the time limit applicable to substances listed in Part II of that Schedule (*regulation 13*);
- (g) amending the restrictions and specifications in the entry in Schedule 2A relating to products obtained by bacterial fermentation (*regulation 14*);
- (h) inserting new entries and amending or removing some existing ones in the specifications set out in Schedule 2B (*regulation 15 and Schedule 6*);
- (i) adding a provision to the basic rules for overall and specific migration testing using food simulants set out in Part I of Schedule 4, to allow for migration testing to be omitted in the specific circumstances provided for in the Directive (*regulation 16*).

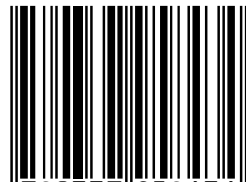
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