
OFFERYNNAU STATUDOL CYMRU

2005 Rhif 1649 (Cy.130)

BWYD, CYMRU

**Rheoliadau Deunyddiau ac Eitemau Plastig mewn
Cysylltiad â Bwyd (Diwygio) (Rhif 2) (Cymru) 2005**

Wedi'u gwneud - - 21 Mehefin 2005
Yn dod i rym - - 24 Mehefin 2005

Mae Cynulliad Cenedlaethol Cymru, drwy arfer y pwerau a roddwyd gan adrannau 16(2), 17(1), 26(1)(a) a (3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(1) ac sydd bellach wedi'u breinio ynddo(2) ac wedi rhoi sylw yn unol ag adran 48(4A) o'r Ddeddf honno i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd ac ar ôl ymgynghori fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor, sy'n pennu egwyddorion cyffredinol a gofynion cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn pennu gweithdrefnau o ran materion diogelwch bwyd(3), yn gwneud y Rheoliadau a ganlyn:

Enwi, cymhwyso a chychwyn

1. Enw'r Rheoliadau hyn yw Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd (Diwygio) (Rhif 2) (Cymru) 2005 sy'n gymwys o ran Cymru a deuant i rym ar 24 Mehefin 2005.

Diwygiadau i Reoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998

2. Diwygir Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998(4) i'r graddau y maent yn gymwys o ran Cymru yn unol â rheoliadau 3 i 16 o'r Rheoliadau hyn.

3. Yn rheoliad 2 (dehongli) —
(a) ym mharagraff (1)—

(1) 1990 p. 16.
(2) Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan Ddeddf Diogelwch Bwyd 1990, i'r graddau yr oeddent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672).
(3) OJ Rhif L31, 1.2.2002, t.1. Diwygiwyd y Rheoliad hwnnw ddiwethaf gan Reoliad (EC) Rhif 1642/2003 Senedd Ewrop a'r Cyngor (OJ Rhif L245, 29.9.2003, t.4).
(4) O.S. 1998/1376, a ddiwygiwyd o ran Cymru gan O.S. 2001/1263 (Cy.70), O.S. 2002/2834 (Cy.272), O.S. 2003/302 (Cy.44) ac O.S. 2005/182 (Cy.15).

- (i) yn lle'r diffiniad o “additive” rhodder ““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) yn y diffiniad o “Council Directive 82/711”, hepgorer y geiriau “as amended” hyd at y diwedd;
- (iii) ar ôl y diffiniad o “Council Directive 82/711” mewnosoder y diffiniadau canlynol—
- ““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(5);
- “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(6);”;
- (iv) hepgorer y diffiniad o “EEA Agreement”;
- (v) yn lle'r diffiniad o “EEA State” rhodder ““EEA State” means a Member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;”;
- (vi) ar ôl y diffiniad o “EEA State” mewnosoder y diffiniad canlynol —
- ““EFSA” means the European Food Safety Authority;”;
- (vii) ar ôl y diffiniad o “preparation” mewnosoder y diffiniad canlynol—
- ““the purity Directives” means Commission Directive [95/31/EC](#) laying down specific criteria of purity concerning sweeteners for use in foodstuffs(7), Commission Directive [95/45/EC](#) laying down purity criteria concerning colours for use in foodstuffs(8) and Commission Directive [96/77/EC](#) laying down specific purity criteria for food additives other than colours or sweeteners(9);”;
- (b) ar ôl paragraff (5) ychwaneger—
- “(6) Any reference in these Regulations to a Community instrument is to be construed as a reference to that instrument as amended at the time the Plastic Materials and Articles in Contact with Food (Amendment) (No. 2) (Wales) Regulations 2005 were made.”.
- 4.** Yn rheoliad 4 (cyfyngiad ar ddefnyddio monomerau wrth weithgynhyrchu deunyddiau ac eitemau plastig)—
- (a) ym mharagraff (2) hepgorer is-baragraffau (a) a (b);
- (b) ym mharagraff (5)(b)(ii) ar ôl y gair “material” ym mhob achos mewnosoder y geiriau “or article”.
- 5.** Yn rheoliad 5 (cyfyngiad ar ddefnyddio ychwanegion wrth weithgynhyrchu deunyddiau ac eitemau plastig)—
- (a) ym mharagraff (1) ychwaneger ar ôl is-baragraff (d)—
- (e) any food additive authorised by Council Directive 89/107 or any flavouring authorised by Council Directive 88/388 that migrates into food —

(5) OJ Rhif L184, 15.7.88, t.61. Diwygiwyd y Gyfarwyddeb hon ddiwethaf gan Reoliad (EC) Rhif 1882/2003 Senedd Ewrop a'r Cyngor (OJ Rhif L284, 31.10.2003, t.1.)

(6) OJ Rhif L40, 11.2.89, t.27. Diwygiwyd y Gyfarwyddeb hon ddiwethaf gan Reoliad (EC) Rhif 1882/2003.

(7) OJ Rhif L178, 28.7.95, t.1. Diwygiwyd y Gyfarwyddeb hon ddiwethaf gan Gyfarwyddeb y Comisiwn 2004/46 (OJ Rhif L114, 21.4.2004, t.15).

(8) OJ Rhif L226, 22.9.95, t.1. Diwygiwyd y Gyfarwyddeb hon ddiwethaf gan Gyfarwyddeb y Comisiwn 2004/47 (OJ Rhif L113, 20.4.2004, t.24).

(9) OJ Rhif L339, 30.12.96, t.1. Diwygiwyd y Gyfarwyddeb hon ddiwethaf gan Gyfarwyddeb y Comisiwn 2003/95 (OJ Rhif L283, 31.10.2003, t.71).

- (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) ym mharagraff (4)(b)(ii) ar ôl y gair “material” ym mhob achos mewnosoder y geiriau “or article”.

6. Ar ôl rheoliad 5A mewnosoder y rheoliad canlynol—

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

5B.—(1) This regulation applies where a person 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 the laws of England and Wales, 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. Yn lle rheoliad 8 (labelu) rhodder y canlynol —

“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 is to 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. Yn rheoliad 10 (tramgwyddau) —

(a) ym mharagraff (1) yn lle'r ffigur “8(1)”, rhodder y ffigur “8”;

(b) ar ôl paragraff (24) ychwaneger —

“(25) In any proceedings for an offence under these Regulations it is 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) (No. 2) (Wales) Regulations 2005 had not been in force at the time that act occurred.”.

9. Yn Atodlen 1, Rhan 1—

- (a) yn Adran A (monomerau a awdurdodwyd heb derfyn amser) —
- (i) mewnosoder yn y drefn rifo briodol y cofnodion a nodir yn Atodlen 1 i'r Rheoliadau hyn;
 - (ii) yn lle eitemau 15A, 39, 70, 120B, 147, 147A, 147B a 188 rhodder y cofnodion a nodir yn Atodlen 2 i'r Rheoliadau hyn;
 - (iii) hepgorer eitemau 76B a 76C a'u cofnodion cyfatebol;
- (b) hepgorer Adrannau B a C.
- 10.** Yn Atodlen 1, Rhan II (atodol) paragraff 4—
- (a) ar ddiwedd nodyn (21) yn lle “and 18670,” rhodder “,18670, 54880 a 59280”;
 - (b) ar ôl nodyn (25) ychwaneger y canlynol—
 - “(27) QMA(T) in this case means that the restriction is not to 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 is not to 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 is not to 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 isoctane as substitute of simulant D (unstable).
 - (33) QMA(T) in this case means that the restriction is not to be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.”
- 11.** Yn Atodlen 2, Rhan I (rhestr anghyflawn o ychwanegion a ddefnyddir wrth weithgynhyrchu deunyddiau ac eitemau plastig) —
- (a) mewnosoder yn y drefn rifo briodol y cofnodion a nodir yn Atodlen 3 i'r Rheoliadau hyn;
 - (b) yn lle eitemau 60A a 198A rhodder y cofnodion a nodir yn Atodlen 4 i'r Rheoliadau hyn;
 - (c) hepgorer eitemau 112, 173A, 195C a 240 gyda'u cofnodion cyfatebol.
- 12.** Yn Atodlen 2, Rhan II (rhestr anghyflawn o ychwanegion a ddefnyddir wrth weithgynhyrchu deunyddiau ac eitemau plastig y mae paragraff 5 o Ran III o Atodlen 2 yn gymwys iddi) —
- (a) mewnosoder yn y drefn rifo briodol y cofnodion a nodir yn Atodlen 5 i'r Rheoliadau hyn;
 - (b) hepgorer eitemau 28, 80 a 111A gyda'u cofnodion cyfatebol.
- 13.** Yn Atodlen 2, Rhan III (atodol) —
- (a) ym mharagraff 4—
 - (i) yn nodyn (8), mewnosoder yn y drefn rifo briodol “38000” a “67896”;
 - (ii) yn nodyn (10), ar ôl “levels” mewnosoder “(expressed as iodine)”;
 - (iii) ar ddiwedd nodyn (21), yn lle “and 18670,” rhodder “, 18670, 54880 a 59280”;
 - (iv) ar ôl nodyn (24) ychwaneger y canlynol—
 - “(26) QMA(T) in this case means that the restriction is not to 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 is not to 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 is not to 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 is not to 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 is not to 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 isooctane as substitute of stimulant D (unstable).

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

(b) ym mharagraff 5 yn lle “1st January 2004” rhodder “1st July 2006”.

14. Yn Atodlen 2A (cynhyrchion a gafwyd drwy eplesu bacterol) yn lle'r cofnod yn y golofn sy'n dwyn y pennawd “restrictions and specifications” rhodder y canlynol —

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

15. Yn lle Atodlen 2B (manylebau) rhodder y tabl a nodir yn Atodlen 6 i'r Rheoliadau hyn.

16. Yn lle paragraff 4(b) o Ran I (rheolau sylfaenol) o Atodlen 4 (profion ymfudo cyffredinol a phenodol gan ddefnyddio efelychwyr bwyd) rhodder —

“(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.”.

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(10)

21 Mehefin 2005

D. Elis-Thomas
Llywydd y Cynulliad Cenedlaethol

Statws This is the original version (as it was originally made).

ATODLEN 1

Rheoliad 9(a)(i)

(COFNODION I'W MEWNOSOD YN ADRAN A O RAN I O ATODLEN 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

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions and specifications</i>
135BM	20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	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

ATODLEN 2

Rheoliad 9(a)(ii)

(COFNODION I'W RHOI YN LLE COFNODION YN ADRAN A O RAN I O ATOCLEN 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 = 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

Statws This is the original version (as it was originally made).

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions and specifications</i>
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	

ATODLEN 3

Rheoliad 11(a)

(COFNODION I'W MEWNOSOD YN RAN I O ATODLEN 22)

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions and specifications</i>
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%

<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions and specifications</i>
				(w/w) in contact with foods other of 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	—	15,7-di-tert-Butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: 3(a)5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80-100% w/w); and 3(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	

Statws This is the original version (as it was originally made).

<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions and specifications</i>
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 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 C12-C18 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	

ATODLEN 4

Rheoliad 11(b)

(COFNODION I'W RHOI YN LLE COFNODION YN RAN I O ATODLEN 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

ATODLEN 5

Rheoliad 12(a)

(COFNODION I'W MEWNOSOD YN RAN II O ATODLEN 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>
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⁾

Statws This is the original version (as it was originally made).

<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions and specifications</i>
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⁾
101A	86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as S02)
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 S02)
102C	87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg ⁽³⁰⁾ (expressed as S02)
110A	94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg

ATODLEN 6

Rheoliad 15

(TABL I'W ROI YN LLE TABL YN ATODLEN 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)

<i>Item</i>	<i>PM/REF No.</i>	<i>Specifications</i>
2	16690	Divinylbenzene It may contain up to 45% (m/m) of Ethylvinylbenzene
3	18888	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer <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> $\begin{array}{cccc} & & \text{CH}_3 & \\ & & & \\ \text{CH}_3 & & \text{O} & & \text{CH}_2 & & \text{O} \\ & & & & & & \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m-(\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n \end{array}$ <p>where $n / (m + n)$ greater than 0 and less or equal to 0.25</p> <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>

Statws This is the original version (as it was originally made).

<i>Item</i>	<i>PM/REF No.</i>	<i>Specifications</i>
		<p>Characteristics</p> <p>Identification tests:</p> <p>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> <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>
4	23547	<p>Polydimethylsiloxane (MW > 6800)</p> <p>Minimum viscosity 100 centistokes at 25°C</p>
5	25385	<p>Triallylamine</p> <p>40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1.5 grams of hydrogel.</p> <p>For use only in hydrogels intended for non-direct food contact use.</p>
6	38320	<p>4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl) stilbene</p> <p>Not more than 0.05% w/w (quantity of substance used / quantity of the formulation)</p>
7	43680	<p>Chlorodifluoromethane Content of chlorofluoromethane less than 1 substance</p>
8	47210	<p>Dibutylthiostannoic acid polymer</p> <p>Molecular unit = (C₈H₁₈S₃Sn₂)_n (n = 1,5-2)</p>
9	76721	<p>Polydimethylsiloxane (Mw > 6800)</p> <p>Minimum viscosity 100 × 10⁻⁶ m²/s (= 100 centistokes) at 25°C</p>
10	77895	<p>Polyethyleneglycol (EO = 2—6) monoalkyl (C₁₆—C₁₈) ether</p> <p>The composition of this mixture is as follows:</p> <p>— polyethyleneglycol (EO = 2—6) monoalkyl (C₁₆—C₁₈) ether (approximately 28%)</p>

<i>Item</i>	<i>PM/REF No.</i>	<i>Specifications</i>
		<ul style="list-style-type: none"> — fatty alcohols (C₁₆—C₁₈) (approximately 48%) — ethyleneglycol monoalkyl (C₁₆—C₁₈) ether (approximately 24%)
11	83595	<p>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</p> <p>Composition</p> <ul style="list-style-type: none"> — 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) — 4-Biphenylene-0,0-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 91362-37-7) (11-19% w/w) — Tris (2,4-di-tert-butylphenyl) phosphite (CAS No. 31570-04-4) (9-18% w/w) — 4,4'-Biphenylene-0,0-bis [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) <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>Soyabean 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 has 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 has 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 note 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

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

1. Mae'r Rheoliadau hyn sy'n gymwys o ran Cymru, yn diwygio ymhellach Reoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998 ([O.S.1998/1376](#), “Rheoliadau 1998”), sy'n gymwys i Brydain Fawr gyfan. Mae'r Rheoliadau hyn yn gweithredu yng Nghymru Gyfarwyddeb y Comisiwn 2004/19/EC (OJ Rhif L71, 10.3.2004, t.8) sy'n diwygio Cyfarwyddeb y Comisiwn [2002/72/EC](#) (OJ Rhif L220, 15.8.2002, t.18), (“y Gyfarwyddeb”) ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd.

2. Mae'r Rheoliadau yn diwygio Rheoliadau 1998 drwy —

- (a) diwygio'r diffiniad o “additive” er mwyn bod yn gyson â'r Gyfarwyddeb (rheoliad 3(a)(i));
- (b) tynnu'r cyfeiriadau at restrï o sylweddau y mae eu hawdurdodiad bellach wedi darford (rheoliad 4(a));
- (c) estyn i eitemau ddarpariaethau rheoliad 4(5) o Reoliadau 1998 a oedd cyn hynny'n gymwys i ddeunyddiau yn unig (rheoliad 4(b));
- (ch) ychwanegu cyfyngiad at ddefnyddio ychwanegion wrth weithgynhyrchu deunyddiau ac eitemau plastig sy'n ymwneud â sylweddau a ddefnyddir hefyd fel ychwanegion neu gyflasynnau bwyd (rheoliad 5(a));
- (d) estyn i eitemau ddarpariaethau rheoliad 5(4) o Reoliadau 1998 a oedd cyn hynny'n gymwys i ddeunyddiau yn unig (rheoliad 5(b));
- (dd) gwneud darpariaeth am y weithdrefn sydd i'w dilyn a'r terfynau amser sydd i'w cadw gan unrhyw berson sy'n dymuno cynnwys ychwanegyn yn rhestr y Gymuned o ychwanegion awdurdodedig (rheoliad 6);
- (e) diwygio'r gofynion labelu ar gyfer deunyddiau ac eitemau plastig yn y cyfnod cyn manwerthu er mwyn ei gwneud yn ofynnol i wybodaeth ychwanegol gael ei rhoi (rheoliad 7);
- (f) gwneud diwygiad canlyniadol i reoliad 10 (tramgwyddau) a achoswyd oherwydd y diwygiad i'r gofynion labelu (rheoliad 8(a));
- (ff) darparu amddiffyniad i doriad yn Rheoliadau 1998 fel y'u diwygiwyd ddiwethaf gan y Rheoliadau hyn o ran deunyddiau neu eitemau plastig a weithgynhyrchir neu a fewnforir i'r Gymuned Ewropeaidd cyn 1 Mawrth 2006 (rheoliad 8(b)).

3. Maent hefyd yn diwygio'r Atodlenni i Reoliadau 1998 drwy —

- (a) mewnosod cofnodion newydd, a diwygio neu ddileu rhai o'r cofnodion presennol, yn y rhestr o fonomerau a awdurdodwyd heb derfyn amser yn adran A o Ran I o Atodlen 1 (rheoliad 9(a) ac Atodlenni 1 & 2);
- (b) tynnu'r rhestr o gofnodion ar gyfer monomerau a awdurdodwyd gyda therfyn amser a ddaeth bellach i ben (rheoliad 9(b));
- (c) ychwanegu manylebau atodol pellach at Ran II o Atodlen 1 (rheoliad 10);
- (ch) mewnosod cofnodion newydd a diwygio neu dynnu rhai o'r cofnodion presennol yn y rhestr o ychwanegion a ddefnyddir wrth weithgynhyrchu deunyddiau ac eitemau plastig yn Rhan 1 o Atodlen 2 (rheoliad 11 ac Atodlenni 3 a 4);

- (d) mewnosod cofnodion newydd a thynnu rhai o'r cofnodion presennol yn y rhestr o ychwanegion a ddefnyddir wrth weithgynhyrchu deunyddiau ac eitemau plastig a nodir yn Rhan II o Atodlen 2 (rheoliad 12 ac Atodlen 5);
 - (dd) ychwanegu manylebau atodol pellach at Ran III o Atodlen 2, ac estyn y terfyn amser sy'n gymwys i sylweddau a restrir yn Rhan II o'r Atodlen honno (rheoliad 13);
 - (e) diwygio'r cyfyngiadau a'r manylebau yn y cofnod yn Atodlen 2A ynghylch cynhyrchion a gafwyd drwy eplesu bacterol (rheoliad 14)
 - (f) mewnosod cofnodion newydd a diwygio neu dynnu rhai o'r cofnodion presennol yn y manylebau a nodir yn Atodlen 2B (rheoliad 15 ac Atodlen 6);
 - (ff) ychwanegu darpariaeth at y rheolau sylfaenol ar gyfer profion ymfudo cyffredinol a phenodol gan ddefnyddio efelychwyr bwyd a nodir yn Rhan 1 o Atodlen 4, i ganiatáu hepgor profion ymfudo yn yr amgylchiadau penodol y darperir ar eu cyfer yn y Gyfarwyddeb (rheoliad 16).
4. Mae arfarniad rheoliadol yn unol ag adran 65 o Ddeddf Llywodraeth Cymru 1998 wedi'i baratoi ar gyfer y rheoliadau hyn a'i osod yn llyfrgell Cynulliad Cenedlaethol Cymru ynghyd â Nodyn Trosi sy'n nodi sut y trosir prif elfennau Cyfarwyddeb y Comisiwn [2004/19/EC](#) yn y Rheoliadau hyn. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Wood Street, Caerdydd CF10 1EW.