

COMMISSION DIRECTIVE 2002/72/EC
of 6 August 2002
relating to plastic materials and articles intended to come into contact with foodstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs ⁽²⁾, as last amended by Directive 2002/17/EC ⁽³⁾, has been frequently and substantially amended; for reasons of clarity and rationality, it should therefore be consolidated.
- (2) Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs.
- (3) In order to achieve this objective in the case of plastic materials and articles, a suitable instrument is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC, the general provisions of which are also applicable to the case in question.
- (4) The scope of this Directive must coincide with that of Council Directive 82/711/EEC ⁽⁴⁾.
- (5) Since the rules established in this Directive are not suitable for ion-exchange resins, these materials and articles will be covered by a subsequent specific Directive.
- (6) Silicones should be regarded as elastomeric materials rather than plastic materials and therefore should be excluded from the definition of plastic.
- (7) The establishment of a list of approved substances accompanied by a limit on overall migration and, where necessary, by other specific restrictions will be sufficient to achieve the objective laid down in Article 2 of Directive 89/109/EEC.

- (8) Besides the monomers and other starting substances fully evaluated and authorised at Community level, there are also monomers and starting substances evaluated and authorised in at least one Member State which may continue to be used pending their evaluation by the Scientific Committee on Food and the decision on their inclusion in the Community list; this Directive will accordingly be extended in due course to the substances and sectors provisionally excluded.
- (9) The current list of additives is an incomplete list inasmuch as it does not contain all the substances which are currently accepted in one or more Member States; accordingly, these substances continue to be regulated by national laws pending a decision on inclusion in the Community list.
- (10) This Directive establishes specifications for only a few substances. The other substances, which may require specifications, therefore remain regulated in this respect by national laws pending a decision at Community level.
- (11) For certain additives the restrictions established in this Directive cannot yet be applied in all situations pending the collection and evaluation of all the data needed for a better estimation of the exposure of the consumer in some specific situations; therefore, these additives appear in a list other than that of the additives fully regulated at Community level.
- (12) Directive 82/711/EEC lays down the basic rules necessary for testing migration of the constituents of plastic materials and articles and Council Directive 85/572/EEC ⁽⁵⁾ establishes the list of simulants to be used in the migration tests.
- (13) The determination of a quantity of a substance in a finished material or article is simpler than the determination of its specific migration level. The verification of compliance through the determination of quantity rather than specific migration level should therefore be permitted under certain conditions.
- (14) For certain types of plastics the availability of generally recognised diffusion models based on experimental data allows the estimation of the migration level of a substance under certain conditions, therefore avoiding complex, costly and time-consuming testing.

⁽¹⁾ OJ L 40, 11.2.1989, p. 38.

⁽²⁾ OJ L 75, 21.3.1990, corrected by OJ L 349, 13.12.1990, p. 26.

⁽³⁾ OJ L 58, 28.2.2002, p. 19.

⁽⁴⁾ OJ L 297, 23.10.1982, p. 26. Directive as last amended by Directive 97/48/EC (OJ L 222, 12.8.1997, p. 10).

⁽⁵⁾ OJ L 372, 31.12.1985, p. 14.

- (15) The overall migration limit is a measure of the inertness of the material and prevents an unacceptable change in the composition of the foodstuffs, and, moreover, reduces the need for a large number of specific migration limits or other restrictions, thus giving effective control.
- (16) Council Directive 78/142/EEC ⁽¹⁾ lays down limits for the quantity of vinyl chloride present in plastic materials and articles prepared with this substance and for the quantity of vinyl chloride released by these materials and articles, and Commission Directives 80/766/EEC ⁽²⁾ and 81/432/EEC ⁽³⁾ establish the Community methods of analysis for controlling these limits.
- (17) In view of potential liability, there is a need for the written declaration provided for in Article 6(5) of Directive 89/109/EEC whenever professional use is made of plastic materials and articles which are not by their nature clearly intended for food use.
- (18) Commission Directive 80/590/EEC ⁽⁴⁾ determines the symbol that may accompany any material and article intended to come into contact with foodstuffs.
- (19) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of plastic materials and articles intended to come into contact with foodstuffs, to lay down rules on the definition of plastics and permitted substances. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (20) In accordance with Article 3 of Directive 89/109/EEC, the Scientific Committee on Food has been consulted on the provisions liable to affect public health.
- (21) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (22) This Directive should be without prejudice to the deadlines set out in Annex VII, Part B within which the Member States are to comply with Directive 90/128/EEC, and the acts amending it,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.
2. This Directive shall apply to plastic materials and articles and parts thereof:
- (a) consisting exclusively of plastics; or

- (b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs are intended for that purpose.

3. For the purposes of this Directive, 'plastics' shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as 'plastics':

- (a) varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC ⁽⁵⁾;
- (b) elastomers and natural and synthetic rubber;
- (c) paper and paperboard, whether modified or not by the addition of plastics;
- (d) surface coatings obtained from:
- paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
 - mixtures of the waxes listed in the first indent with each other and/or with plastics,
- (e) ion-exchange resins;
- (f) silicones.

4. This Directive shall not apply, until further action by the Commission, to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

Article 2

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);
- (b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
- (c) caps, gaskets, stoppers or similar devices for sealing.

⁽¹⁾ OJ L 44, 15.2.1978, p. 15.

⁽²⁾ OJ L 213, 16.8.1980, p. 42.

⁽³⁾ OJ L 167, 24.6.1981, p. 6.

⁽⁴⁾ OJ L 151, 19.6.1980, p. 21.

⁽⁵⁾ OJ L 93, 17.4.1993, p. 27. Directive amended by Directive 93/111/EC (OJ L 310, 14.12.1993, p. 41).

Article 3

1. Only those monomers and other starting substances listed in Annex II, Sections A and B, may be used for the manufacture of plastic materials and articles subject to the restrictions specified.

2. By way of derogation from the first paragraph the monomers and other starting substances listed in Annex II, Section B, may continue to be used until 31 December 2004 at latest, pending their evaluation by the Scientific Committee on Food.

3. The list in Annex II, Section A, may be amended:

- either by adding substances listed in Annex II, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or
- by including 'new substances', i.e. substances which are listed neither in Section A nor in Section B of Annex II, according to Article 3 of Directive 89/109/EEC.

4. No Member State shall authorise any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

5. The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances 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, etc.,
- epoxy resins,
- adhesives and adhesion promoters,
- printing inks.

Article 4

An incomplete 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, Sections A and B.

For the substances in Annex III, Section B, the specific migration limits are applied as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.

Article 5

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

Article 6

1. General specifications related to plastic materials and articles are laid down in Annex V, Part A. Other specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, Part B.

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

Article 7

The specific migration limits in the list set out in Annex II 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 materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuffs in contact therewith.

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

Article 8

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC and the further provisions set out in Annex I.

2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

3. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.

4. The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

Article 9

1. At the marketing stages other than the retail stages, the plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6(5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to plastic materials and articles, which by their nature are clearly intended to come into contact with foodstuffs.

Article 10

1. Directive 90/128/EEC, as amended by the Directives set out in Annex VII, Part A, is hereby repealed without prejudice to the obligations of the Member States in respect of the deadlines for transposition and application laid down in Annex VII, Part B.

2. References to the repealed Directives shall be construed as references to this Directive and be read in accordance with the correlation table set out in Annex VIII.

Article 11

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

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 6 August 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE WITH THE MIGRATION LIMITS**General provisions**

1. When comparing the results of the migration tests specified in the Annex to Directive 82/711/EEC, the specific gravity of all the simulants should conventionally be assumed to 1. Milligrams of substance(s) released per litre of simulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in Directive 85/572/EEC, to milligrams of substance(s) released per kilogram of foodstuff.
2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m \cdot a_2}{a_1 \cdot q} \cdot 1\,000$$

Where:

M is the migration in mg/kg;

m is the mass in mg of substance released by the sample as determined by the migration test;

a_1 is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm² of the material or article in real conditions of use;

q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.

The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.

The migration testing of caps, gaskets, stoppers or similar devices for sealing must be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.

It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in Article 8 of the present Directive, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.
5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in Directives 82/711/EEC and 85/572/EEC are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue.

If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.

The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.

Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determined. One of these possible modifications is described below.

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M^1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M^2 and M^3 , respectively).

The material or article shall be deemed to be in compliance provided that either M^1 or $M^3 - M^2$ do not exceed the overall migration limit.

7. A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Directive.

The following analytical tolerances have been observed:

- 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,
- 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

8. Without prejudice to the provisions of Article 3(2) of Directive 82/711/EEC, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint.

In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit.

ANNEX II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Annex contains the list of monomers or other starting substances. The list includes:
 - substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
 - natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list,
 - substances used to modify existing natural or synthetic substances.
2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing '... acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned. In each case the meaning of the term 'salts' is 'salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.
3. The list also does not include the following substances although they may be present:
 - (a) substances which could be present in the finished product as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
 - (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;
 - (c) mixtures of the authorised substances.

The materials and articles, which contain the substances indicated under points (a), (b) and (c) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality as regards the purity criteria.
5. The list contains the following information:
 - column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
 - column 3 (Name): the chemical name,
 - column 4 (Restrictions and/or specifications): These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer.
6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in Einecs and the CAS Registry, the CAS number in the CAS Registry shall apply.
8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:
 - DL = Detection limit of the method of analysis;
 - FP = Finished material or article;
 - NCO = Isocyanate moiety;
 - ND = not detectable. For the purpose of this Directive 'not detectable' means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;

- QM = Maximum permitted quantity of the 'residual' substance in the material or article;
- QM(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the quantity of the substance in the material or article should 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;
- QMA = Maximum permitted quantity of the 'residual' substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should 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;
- QMA(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should 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;
- SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Directive the specific migration of the substance should 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;
- SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the specific migration of the substances should 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.

Section A

List of authorised monomers and other starting substances

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	SML(T) = 6 mg/kg ⁽²⁾
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
10690	000079-10-7	Acrylic acid	
10750	002495-35-4	Acrylic acid, benzyl ester	
10780	000141-32-2	Acrylic acid, n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid, tert-butyl ester	
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	QMA = 0,05 mg/6 dm ²
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg ⁽¹⁾
11470	000140-88-5	Acrylic acid, ethyl ester	
11510	000818-61-1	Acrylic acid, hydroxyethyl ester	See 'Acrylic acid, monoester with ethyleneglycol'
11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0,05 mg/6 dm ²
11590	000106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
11890	002499-59-4	Acrylic acid, n-octyl ester	
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = ND (DL = 0,020 mg/kg, analytical tolerance included)
12130	000124-04-9	Adipic acid	
12265	004074-90-2	Adipic acid, divinyl ester	QM = 5 mg/kg in FP. Or use only as comonomer
12280	002035-75-8	Adipic anhydride	
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₂₂)	
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5 trimethylcyclohexane	SML = 6 mg/kg
12761	000693-57-2	12-Aminododecanoic acid	SML = 0,05 mg/kg
12763	000141-43-5	2-Aminoethanol	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
12765	084434-12-8	N-(2-Aminoethyl)-beta-alanine, sodium salt	SML = 0,05 mg/kg
12788	002432-99-7	11-Aminoundecanoic acid	SML = 5 mg/kg
12789	007664-41-7	Ammonia	
12820	000123-99-9	Azelaic acid	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
12970	004196-95-6	Azelaic anhydride	
13000	001477-55-0	1,3-Benzenedimethanamine	SML= 0,05 mg/kg
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	QMA = 0,05 mg/6 dm ² (measured as 1,3,5-Benzenetricarboxylic acid)
13075	000091-76-9	Benzoguanamine	See '2,4-Diamino-6-phenyl-1,3,5-triazine'
13090	000065-85-0	Benzoic acid	
13150	000100-51-6	Benzyl alcohol	
13180	000498-66-8	Bicyclo(2.2.1)hept-2-ene (=Norbornene)	SML= 0,05 mg/kg
13210	001761-71-3	Bis(4-aminocyclohexyl)methane	SML= 0,05 mg/kg
13326	000111-46-6	Bis(2-hydroxyethyl)ether	See 'Diethyleneglycol'
13380	000077-99-6	2,2-Bis(hydroxymethyl)-1-butanol	See '1,1,1-Trimethylolpropane'
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
13395	004767-03-7	2,2-Bis(hydroxymethyl)propionic acid	QMA = 0,05 mg/6 dm ²
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 3 mg/kg
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (=BADGE)	According to Commission Directive 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (OJ L 51, 22.2.2002, p. 27)
13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	SML = 0,05 mg/kg
13550	000110-98-5	Bis(hydroxypropyl) ether	See 'Dipropyleneglycol'
13560	0005124-30-1	Bis(4-isocyanatocyclohexyl)methane	See 'Dicyclohexylmethane-4,4'-diisocyanate'
13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone	SML = 1,8 mg/kg
13607	000080-05-7	Bisphenol A	See '2,2-Bis(4-Hydroxyphenyl)propane'
13610	001675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See '2,2-Bis(4-Hydroxyphenyl)propane bis(2,3-epoxypropyl) ether'
13614	038103-06-9	Bisphenol A bis(phthalic anhydride)	See '2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)'
13617	000080-09-1	Bisphenol S	See '4,4'-Dihydroxydiphenyl sulphone'
13620	010043-35-3	Boric acid	SML(T) = 6 mg/kg ⁽²³⁾ (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p. 32).
13630	000106-99-0	Butadiene	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
13690	000107-88-0	1,3-Butanediol	
13720	000110-63-4	1,4-Butanediol	SML(T) = 0,05 mg/kg ⁽²⁴⁾
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl)ether	QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)
13810	000505-65-7	1,4-Butanediol formal	QMA = 0,05 mg/6 dm ²
13840	000071-36-3	1-Butanol	
13870	000106-98-9	1-Butene	
13900	000107-01-7	2-Butene	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
13932	000598-32-3	3-Buten-2-ol	QMA = ND (DL = 0,02 mg/6 dm ²) To be used only as comonomer for the preparation of polymetric additive
14020	000098-54-4	4-tert-Butylphenol	SML = 0,05 mg/kg
14110	000123-72-8	Butyraldehyde	
14140	000107-92-6	Butyric acid	
14170	000106-31-0	Butyric anhydride	
14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg ⁽⁵⁾
14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg ⁽⁵⁾ (expressed as Caprolactam)
14320	000124-07-2	Caprylic acid	
14350	000630-08-0	Carbon monoxide	
14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
14411	008001-79-4	Castor oil	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
14570	000106-89-8	1-Chloro-2,3-epoxypropane	See 'Epichlorohydrin'
14650	000079-38-9	Chlorotrifluoroethylene	QMA = 0,5 mg/6 dm ²
14680	000077-92-9	Citric acid	
14710	000108-39-4	<i>m</i> -Cresol	
14740	000095-48-7	<i>o</i> -Cresol	
14770	000106-44-5	<i>p</i> -Cresol	
14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
14880	000105-08-8	1,4-Cyclohexanedimethanol	See '1,4-Bis(Hydroxymehtyl)cyclohexane'
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
15030	000931-88-4	Cyclooctene	SML = 0,05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Directive 85/572/EEC
15070	001647-16-1	1,9-Decadiene	SML = 0,05 mg/kg
15095	000334-48-5	Decanoic acid	
15100	000112-30-1	1-Decanol	
15130	000872-05-9	1-Decene	SML = 0,05 mg/kg
15250	000110-60-1	1,4-Diaminobutane	
15272	000107-15-3	1,2-Diaminoethane	See 'Ethylenediamine'
15274	000124-09-4	1,6-Diaminohexane	See 'Hexamethylenediamine'
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm ²
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
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15610	000080-07-9	4,4'-Dichlorodiphenyl sulphone	SML = 0,05 mg/kg

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
15700	005124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg ⁽³⁾
15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg
15820	000345-92-6	4,4'-Difluorbenzophenone	SML = 0,05 mg/kg
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾
16000	000092-88-6	4,4'-Dihydroxybiphenyl	SML = 6 mg/kg
16090	000080-09-1	4,4'-Dihydroxydiphenyl sulphone	SML = 0,05 mg/kg
16150	000108-01-0	Dimethylaminoethanol	SML = 18 mg/kg
16240	000091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
16360	000576-26-1	2,6-Dimethylphenol	SML = 0,05 mg/kg
16390	000126-30-7	2,2'-Dimethyl-1,3-propanediol	SML = 0,05 mg/kg
16450	000646-06-0	1,3-Dioxolane	SML = 0,05 mg/kg
16480	000126-58-9	Dipentaerythritol	
16570	004128-73-8	Diphenylether-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
16600	005873-54-1	Diphenylmethane-2,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
16630	000101-68-8	Diphenylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
16650	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg ⁽²⁵⁾
16660	000110-98-5	Dipropyleneglycol	
16690	001321-74-0	Divinylbenzene	QMA = 0,01 mg/6 dm ² or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Annex V
16694	013811-50-2	N,N'-Divinyl-2-imidazolidinone	QM = 5 mg/kg in FP
16697	000693-23-2	n-Dodecanedioic acid	
16704	000112-41-4	1-Dodecene	SML = 0,05 mg/kg
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg ⁽³⁾
17005	000151-56-4	Ethylenimine	SML = ND (DL = 0,01 mg/kg)
17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
17160	000097-53-0	Eugenol	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
17170	061788-47-4	Fatty acids, coco	
17200	068308-53-2	Fatty acids, soya	
17230	061790-12-3	Fatty acids, tall oil	
17260	000050-00-0	Formaldehyde	
17290	000110-17-8	Fumaric acid	
17530	000050-99-7	Glucose	
18010	000110-94-1	Glutaric acid	
18070	000108-55-4	Glutaric anhydride	
18100	000056-81-5	Glycerol	
18220	068564-88-5	N-Heptylaminoundecanoic acid	SML = 0,05 mg/kg ⁽¹⁾
18250	000115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	SML = ND (DL = 0,01 mg/kg)
18280	000115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	SML = ND (DL = 0,01 mg/kg)
18310	036653-82-4	1-Hexadecanol	SML = ND (DL = 0,01 mg/kg)
18430	000116-15-4	Hexafluoropropylene	
18460	000124-09-4	Hexamethylenediamine	
18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
18670	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg ⁽²²⁾ (expressed as Formaldehyde)
18820	000592-41-6	1-Hexene	SML = 3 mg/kg
18867	000123-31-9	Hydroquinone	See '1,4-Dihydroxybenzene'
18880	000099-96-7	p-Hydroxybenzoic acid	SML = 0,05 mg/kg
18897	016712-64-4	6-Hydroxy-2-naphthalenecarboxylic acid	
18898	000103-90-2	n-(4-Hydroxyphenyl) acetamide	
19000	000115-11-7	Isobutene	QM = 5 mg/kg in FP
19060	000109-53-5	Isobutyl vinyl ether	
19110	04098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	
19150	000121-91-5	Isophthalic acid	SML = 5 mg/kg
19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg
19243	000078-79-5	Isoprene	See '2-Methyl-1,3-butadiene'
19270	000097-65-4	Itaconic acid	SML = 5 mg/kg
19460	000050-21-5	Lactic acid	
19470	000143-07-7	Lauric acid	
19480	002146-71-6	Lauric acid, vinyl ester	
19490	000947-04-6	Lauro lactam	
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	
19960	000108-31-6	Maleic anhydride	
19975	000108-78-1	Melamine	
19990	000079-39-0	Methacrylamide	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
20020	000079-41-4	Methacrylic acid	SML = 0,05 mg/kg
20050	000096-05-9	Methacrylic acid, allyl ester	
20080	002495-37-6	Methacrylic acid, benzyl ester	
20110	000097-88-1	Methacrylic acid, butyl ester	
20140	002998-18-7	Methacrylic acid, sec-butyl ester	
20170	000585-07-9	Methacrylic acid, tert-butyl ester	SML = 0,05 mg/kg
20260	000101-43-9	Methacrylic acid, cyclohexyl ester	
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0,05 mg/kg
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)-ethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA = 0,02 mg/6 dm ²
20890	000097-63-2	Methacrylic acid, ethyl ester	SML = ND (DL = 0,020 mg/kg, analytical tolerance included)
21010	000097-86-9	Methacrylic acid, isobutyl ester	
21100	004655-34-9	Methacrylic acid, isopropyl ester	
21130	000080-62-6	Methacrylic acid, methyl ester	
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	
21280	002177-70-0	Methacrylic acid, phenyl ester	
21340	002210-28-8	Methacrylic acid, propyl ester	
21460	000760-93-0	Methacrylic anhydride	
21490	000126-98-7	Methacrylonitrile	
21520	001561-92-8	Methallylsulphonic acid, sodium salt	
21550	000067-56-1	Methanol	QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
21640	000078-79-5	2-Methyl-1,3-butadiene	
21730	000563-45-1	3-Methyl-1-butene	QMA = 0,006 mg/6 dm ² . For use only in Polypropylene
21765	106246-33-7	4,4'-Methylenebis(3-chloro-2,6-diethylaniline)	QMA = 0,05 mg/6 dm ²
21821	000505-65-7	1,4-(Methylenedioxy)butane	See '1,4-Butanediol formal'
21940	000924-42-5	N-Methylolacrylamide	SML = ND (DL = 0,01 mg/kg)
22150	000691-37-2	4-Methyl-1-pentene	SML = 0,02 mg/kg
22331	025513-64-8	Mixture of (40 % w/w) 1,6-diamino-2,4,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²
22332	028679-16-5	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⁾
22350	000544-63-8	Myristic acid	SML = 5 mg/kg
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	
22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	SML = 0,05 mg/kg
22420	003173-72-6	1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾
22437	000126-30-7	Neopentylglycol	See '2,2-Dimethyl-1,3-propanediol'
22450	009004-70-0	Nitrocellulose	See 'Bicyclo(2.2.1)hept-2-ene'
22480	000143-08-8	1-Nonanol	
22550	000498-66-8	Norbornene	
22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
22600	000111-87-5	1-Octanol	SML = 15 mg/kg
22660	000111-66-0	1-Octene	
22763	000112-80-1	Oleic acid	
22778	007456-68-0	4,4'-Oxybis(benzenesulphonyl azide)	QMA = 0,05 mg/6 dm ²
22780	000057-10-3	Palmitic acid	
22840	000115-77-5	Pentaerythritol	
22870	000071-41-0	1-Pentanol	SML = 5 mg/kg
22900	000109-67-1	1-Pentene	
22937	001623-05-8	Perfluoropropylperfluorovinyl ether	
22960	000108-95-2	Phenol	SML = 0,05 mg/kg
23050	000108-45-2	1,3-Phenylenediamine	
23155	000075-44-5	Phosgene	
23170	007664-38-2	Phosphoric acid	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
23175	000122-52-1	Phosphorous acid, triethyl ester	
23187		Phthalic acid	
23200	000088-99-3	o-Phthalic acid	See 'Carbonyl chloride'
23230	000131-17-9	Phthalic acid, diallyl ester	
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	QM = ND (DL = 1 mg/kg in FP)
23500	000127-91-3	beta-Pinene	
23547	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6 800)	
23590	025322-68-3	Polyethyleneglycol	SML = ND (DL = 0,01 mg/kg)
23651	025322-69-4	Polypropyleneglycol	
23740	000057-55-6	1,2-Propanediol	
23770	000504-63-2	1,3-Propanediol	SML = 0,05 mg/kg
23800	000071-23-8	1-Propanol	
23830	000067-63-0	2-Propanol	
23860	000123-38-6	Propionaldehyde	SML(T) = 6 mg/kg ⁽²⁾ (expressed as Acetaldehyde)
23890	000079-09-4	Propionic acid	
23920	000105-38-4	Propionotic acid, vinyl ester	
23950	000123-62-6	Propionic anhydride	SML = 0,05 mg/kg (expressed as Pyromellitic acid)
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	
24051	000120-80-9	Pyrocatechol	QM = 1 mg/kg in FP
24057	000089-32-7	Pyromellitic anhydride	
24070	073138-82-6	Resin acids and Rosin acids	
24072	000108-46-3	Resorcinol	See '1,3-Dihydroxybenzene'
24073	000101-90-6	Resorcinol diglycidyl ether	

QMA = 0,005 mg/6 dm². Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer.

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
24100	008050-09-7	Rosin	See 'Rosin'
24130	008050-09-7	Rosin gum	
24160	008052-10-6	Rosin tall oil	
24190	009014-63-5	Rosin wood	
24250	009006-04-6	Rubber, natural	
24270	000069-72-7	Salicylic acid	
24280	000111-20-6	Sebacic acid	
24430	002561-88-8	Sebacic anhydride	
24475	001313-82-2	Sodium sulphide	
24490	000050-70-4	Sorbitol	
24520	008001-22-7	Soybean oil	
24540	009005-25-8	Starch, edible	
24550	000057-11-4	Stearic acid	
24610	000100-42-5	Styrene	
24760	026914-43-2	Styrenesuphonic acid	SML = 0,05 mg/kg
24820	000110-15-6	Succinic acid	SML = 0,05 mg/kg SML = 7,5 mg/kg SML(T) = 7,5 mg/kg (expressed as Terephthalic acid) SML = 0,05 mg/kg SML = 0,05 mg/kg SML = 0,6 mg/kg QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾ QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾ QM(T) = 1 mg/kg (expressed as NCO) ⁽²⁶⁾ QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43) QMA = 0,05 mg/6 dm ² In compliance with the specifications laid down in Annex V SML = 30 mg/kg SML = 0,05 mg/kg SML = 6 mg/kg
24850	000108-30-5	Succinic anhydride	
24880	000057-50-1	Sucrose	
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	
24910	000100-21-0	Terephthalic acid	
24940	000100-20-9	Terephthalic acid dichloride	
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25080	001120-36-1	1-Tetradecene	
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluorethylene	
25150	000109-99-9	Tetrahydrofuran	
25180	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	
25240	000091-08-7	2,6-Toluene diisocyanate	
25270	026747-90-0	2,4-Toluene diisocyanate dimer	
25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	
25380	—	Trialkyl acetic acid (C7-C17), vinyl esters (= Vinyl versatate)	
25385	000102-70-5	Triallylamine	
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	
25450	026896-48-0	Tricyclodecanedimethanol	
25510	000112-27-6	Triethyleneglycol	
25600	000077-99-6	1,1,1-Trimethylolpropane	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	SML = 0,05 mg/kg
25900	000110-88-3	Trioxane	QM = 0,05 mg/kg
25910	024800-44-0	Tripropyleneglycol	
25927	027955-94-8	1,1,1-Tris(4-hydroxyphenol)ethane	QM= 0,5 mg/kg in FP. For use only in polycarbonates
25960	000057-13-6	Urea	
26050	000075-01-4	Vinyl chloride	See Council Directive 78/142/EEC
26110	000075-35-4	Vinylidene chloride	QM = 5 mg/kg in FP or SML = ND (DL = 0,05 mg/kg)
26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg
26155	001072-63-5	1-Vinylimidazole	QM = 5 mg/kg in FP
26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 2 mg/kg in FP
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
26360	007732-18-5	Water	In compliance with Directive 98/83/EC

Section B

**List of monomers and other starting substances which may continue to be used pending a decision on inclusion
in Section A**

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
10599/90A	061788-89-4	Acids, fatty, unsaturated (C ₁₈), dimers, distilled	See 'Trimellitic acid'
10599/91	061788-89-4	Acids, fatty, unsaturated (C ₁₈), dimers, non-distilled	
10599/92A	068783-41-5	Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled	
10599/93	068783-41-5	Acids, fatty, unsaturated (C ₁₈), dimers, hydrogenated, non-distilled	
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
13050	000528-44-9	1,2,4-Benzenetricarboxylic acid	
14260	000502-44-3	Caprolactone	
14800	003724-65-0	Crotonic acid	
15730	000077-73-6	Dicyclopentadiene	
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodichloromethane	
17110	016219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	
18370	000592-45-0	1,4-Hexadiene	
18700	000629-11-8	1,6-Hexanediol	
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	
21970	000923-02-4	N-Methylolmethacrylamide	
22210	000098-83-9	alpha-Methylstyrene	
25540	000528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP QM(T) = 5 mg/kg in FP (expressed as Trimellitic acid)
25550	000552-30-7	Trimellitic anhydride	
26230	000088-12-0	Vinylpyrrolidone	

ANNEX III

INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Annex contains the list of:

- (a) substances which are incorporated into plastics to achieve a technical effect in the finished product. They are intended to be present in the finished articles;
- (b) substances used to provide a suitable medium in which polymerization occurs (e.g. emulsifiers, surfactants, buffering agents etc.).

The list does not include the substances, which directly influence the formation of polymers (e.g. the catalytic system).

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing '...acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term 'salts' is 'salts of aluminium ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.

3. The list does not include the following substances although they may be present:

- (a) substances which could be present in the finished product such as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
- (b) mixtures of the authorised substances.

The materials and articles which contain the substances indicated in (a) and (b) shall comply with the requirements stated in article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality as regards the purity criteria.

5. The list contains the following information:

- column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
- column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
- column 3 (Name): the chemical name,
- column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or polymer.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS registry, the CAS number in the CAS registry shall apply.

Section A

Incomplete list of additives fully harmonised at Community level

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
30000	000064-19-7	Acetic acid	SML(T) = 30 mg/kg (?) (expressed as Copper)
30045	000123-86-4	Acetic acid, butyl ester	
30080	004180-12-5	Acetic acid, copper salt	
30140	000141-78-6	Acetic acid, ethyl ester	
30280	000108-24-7	Acetic anhydride	
30295	000067-64-1	Acetone	
30370	—	Acetylacetic acid, salts	
30400	—	Acetylated glycerides	
30610	—	Acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	
30612	—	Acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	
30960	—	Acids, aliph., moncarb. (C ₆ -C ₂₂), esters with polyglycerol	SML = 5 mg/kg
31328	—	Acids, fatty, from animal or vegetable food fats and oils	
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxy-phenyl)ethyl)phenyl ester	
31730	000124-04-9	Adipic acid	
33120	—	Alcohols, aliph, monoh., sat., linear, primary (C ₄ -C ₂₄)	
33350	009005-32-7	Alginate acid	
33801	—	n-Alkyl(C ₁₀ -C ₁₃)benzenesulphonic acid	
34240	—	Alkyl(C ₁₀ -C ₂₀)sulphonic acid, esters with phenols	
34281	—	Alkyl(C ₈ -C ₂₂)sulphuric acids, linear, primary with an even number of carbon atoms	
34475	—	Aluminum calcium hydroxide phosphite, hydrate	SML = 30 mg/kg
34480	—	Aluminium fibers, flakes and powders	
34560	021645-51-2	Aluminium hydroxide	
34690	011097-59-9	Aluminium magnesium carbonate hydroxide	
34720	001344-28-1	Aluminium oxide	
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	
35160	006642-31-5	6-Amino-1,3-dimethyluracil	
35170	000141-43-5	2-Aminoethanol	
35284	000111-41-1	N-(2-aminoethyl)ethanolamine	
			SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
			SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer.

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
35320	007664-41-7	Ammonia	For use only as a blowing agent SML(T) = 1 mg/kg expressed as Barium ⁽¹²⁾ and SML(T) = 6 mg/kg ⁽²³⁾ expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L330, 5.12.1998, p. 32).
35440	001214-97-9	Ammonium bromide	
35600	001336-21-6	Ammonium hydroxide	
35840	000506-30-9	Arachidic acid	
35845	007771-44-0	Arachidonic acid	
36000	000050-81-7	Ascorbic acid	
36080	000137-66-6	Ascorbyl palmitate	
36160	010605-09-1	Ascorbyl stearate	
36640	000123-77-3	Azodicarbonamide	
36840	012007-55-5	Barium tetraborate	
36880	008012-89-3	Beeswax	In compliance with note 9 in Annex VI
36960	003061-75-4	Behenamide	
37040	000112-85-6	Behenic acid	
37280	001302-78-9	Bentonite	
37360	000100-52-7	Benzaldehyde	
37600	000065-85-0	Benzoic acid	
37680	000136-60-7	Benzoic acid, butyl ester	
37840	000093-89-0	Benzoic acid, ethyl ester	
38080	000093-58-3	Benzoic acid, methyl ester	
38160	002315-68-6	Benzoic acid, propyl ester	
38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene	In compliance with the specifications laid down in Annex V
38510	136504-96-6	1,2-Bis(3-Aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	SML = 5 mg/kg
38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene	SML = 0,05 mg/kg ⁽¹⁾
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	SML = 5 mg/kg (sum of phosphite and phosphate)
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl) pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol).
38879	135861-56-2	Bis(3,4-dimethylbenzylidene)sorbitol	SML = 1,8 mg/kg
38950	079072-96-1	Bis(4-ethylbenzylidene)sorbitol	
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	
39890	087826-41-3 069158-41-4 054686-97-4 081541-12-0	Bis(methylbenzylidene)sorbitol	
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethyl hexane	
40120	068951-50-8	Bis(polyethyleneglycol)hydroxymethylphosphonate	
			QMA = 0,05 mg/6 dm ²
			SML = 0,05 mg/kg
			SML = 0,6 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
40320	010043-35-3	Boric acid	SML(T) = 6 mg/kg ⁽²³⁾ (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p.32).
40400	010043-11-5	Boron nitride	SML(T) = 0,05 mg/kg ⁽²⁴⁾
40570	000106-97-8	Butane	
40580	000110-63-4	1,4-Butanediol	
41040	005743-36-2	Calcium butyrate	
41120	010043-52-4	Calcium chloride	
41280	001305-62-0	Calcium hydroxide	
41520	001305-78-8	Calcium oxide	
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	
41680	000076-22-2	Camphor	
41760	008006-44-8	Candelilla wax	
41840	000105-60-2	Caprolactam	SML(T) = 15 mg/kg ⁽⁵⁾
41960	000124-07-2	Caprylic acid	
42160	000124-38-9	Carbon dioxide	
42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg ⁽⁷⁾ (expressed as Copper)
42500	—	Carbonic acid, salts	
42640	009000-11-7	Carboxymethylcellulose	
42720	008015-86-9	Carnauba wax	
42800	009000-71-9	Casein	
42960	064147-40-6	Castor oil, dehydrated	
43200	—	Castor oil, mono-and diglycerides	
43280	009004-34-6	Cellulose	
43300	009004-36-8	Cellulose acetate butyrate	
43360	068442-85-3	Cellulose, regenerated	
43440	008001-75-0	Ceresin	QMA = 0,9 mg/6 dm ²
43515	—	Chlorides of choline esters of coconut oil fatty acids	
44160	000077-92-9	Citric acid	
44640	000077-93-0	Citric acid, triethyl ester	SML(T) = 30 mg/kg ⁽⁷⁾ (expressed as Copper)
45195	007787-70-4	Copper bromide	
45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg ⁽⁷⁾ (expressed as Copper) and SML = 1 mg/kg ⁽¹¹⁾ (expressed as Iodine)
45280	—	Cotton fibers	
45450	068610-51-5	p-Cresol-dicyclopentadiene - isobutylene, copolymer	SML = 0,05 mg/kg
45560	014464-46-1	Cristobalite	
45760	000108-91-8	Cyclohexylamine	
45920	009000-16-2	Dammar	
45940	000334-48-5	n-Decanoic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
46070	010016-20-3	alpha-Dextrin	SML = 6 mg/kg
46080	007585-39-9	beta-Dextrin	
46375	061790-53-2	Diatomaceous earth	
46380	068855-54-9	Diatomaceous earth, soda ash flux-calcined	
46480	032647-67-9	Dibenzylidene sorbitol	
46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	
46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	
46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	In compliance with the specifications laid down in Annex V.
47210	026427-07-6	Dibutylthiostannic acid polymer [= Thiobis(butyl-tin sulphide), polymer]	
47440	000461-58-5	Dicyanodiamide	SML = 0,05 mg/kg
47540	027458-90-8	Di-tert-dodecyl disulfide	
47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg ⁽³⁾
48460	000075-37-6	1,1-Difluoroethane	SML = 0,6 mg/kg
48620	000123-31-9	1,4-Dihydroxybenzene	
48720	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	SML = 1 mg/kg
49540	000067-68-5	Dimethyl sulphoxide	
51200	000126-58-9	Dipentaerythritol	SML = 0,05 mg/kg
51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	
51760	025265-71-8 000110-98-5	Dipropyleneglycol	
52640	016389-88-1	Dolomite	SML(T) = 30 mg/kg ⁽⁷⁾ (expressed as Copper)
52645	010436-08-5	cis-11-Eicosenamide	
52720	000112-84-5	Erucamide	
52730	000112-86-7	Erucic acid	
52800	000064-17-5	Ethanol	
53270	037205-99-5	Ethylcarboxymethylcellulose	
53280	009004-57-3	Ethylcellulose	
53360	000110-31-6	N,N'-Ethylenebisoleamide	
53440	005518-18-3	N,N'-Ethylenebispalmitamide	
53520	000110-30-5	N,N'-Ethylenebistearamide	
53600	000060-00-4	Ethylenediaminetetraacetic acid	SML = 6 mg/kg
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	
53650	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg ⁽³⁾
54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	
54260	009004-58-4	Ethylhydroxyethylcellulose	SML = 0,05 mg/kg
54270	—	Ethylhydroxymethylcellulose	
54280	—	Ethylhydroxypropylcellulose	
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	
54450	—	Fats and oils, from animal or vegetable food sources	SML = 0,05 mg/kg
54480	—	Fats and oils, hydrogenated, from animal or vegetable food sources	
54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [=poly(1-hydroxynaphthylmethane)]	SML = 0,05 mg/kg
55040	000064-18-6	Formic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
55120	000110-17-8	Fumaric acid	
55190	029204-02-2	Gadoleic acid	
55440	009000-70-8	Gelatin	
55520	—	Glass fibers	
55600	—	Glass microballs	
55680	000110-94-1	Glutaric acid	
55920	000056-81-5	Glycerol	
56020	099880-64-5	Glycerol dibehenate	
56360	—	Glycerol, esters with acetic acid	
56486	—	Glycerol, esters with acids, aliph., sat., linear, with an even number of carbon atoms (C ₁₄ -C ₁₈) and with acids, aliph., unsat., linear, with an even number of carbon atoms (C ₁₆ -C ₁₈)	
56487	—	Glycerol, esters with butyric acid	
56490	—	Glycerol, esters with erucic acid	
56495	—	Glycerol, esters with 12-hydroxystearic acid	
56500	—	Glycerol, esters with lauric acid	
56510	—	Glycerol, esters with linoleic acid	
56520	—	Glycerol, esters with myristic acid	
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
56565	—	Glycerol, esters with nonanoic acid	
56570	—	Glycerol, esters with propionic acid	
56580	—	Glycerol, esters with ricinoleic acid	
56585	—	Glycerol, esters with stearic acid	
56610	030233-64-8	Glycerol monobehenate	
56720	026402-23-3	Glycerol monohexanoate	
56800	030899-62-8	Glycerol monolaurate diacetate	
56880	026402-26-6	Glycerol monooctanoate	
57040	—	Glycerol monooleate, ester with ascorbic acid	
57120	—	Glycerol monooleate, ester with citric acid	
57200	—	Glycerol monopalmitate, ester with ascorbic acid	
57280	—	Glycerol monopalmitate, ester with citric acid	
57600	—	Glycerol monostearate, ester with ascorbic acid	
57680	—	Glycerol monostearate, ester with citric acid	
57800	018641-57-1	Glycerol tribehenate	
57920	000620-67-7	Glycerol triheptanoate	
58300	—	Glycine, salts	
58320	007782-42-5	Graphite	
58400	009000-30-0	Guar gum	
58480	009000-01-5	Gum arabic	
58720	000111-14-8	Heptanoic acid	
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
60030	012072-90-1	Hydromagnesite	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
60080	012304-65-3	Hydrotalcite	SML(T) = 30 mg/kg ⁽¹⁹⁾
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	
60180	004191-73-5	4-Hydroxybenzoic acid, isopropyl ester	
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	
60480	003864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	
60560	009004-62-0	Hydroxyethylcellulose	
60880	009032-42-2	Hydroxyethylmethylcellulose	
61120	009005-27-0	Hydroxyethyl starch	
61390	037353-59-6	Hydroxymethylcellulose	
61680	009004-64-2	Hydroxypropylcellulose	
61800	009049-76-7	Hydroxypropyl starch	
61840	000106-14-9	12-Hydroxystearic acid	
62140	006303-21-5	Hypophosphorous acid	
62240	001332-37-2	Iron oxide	
62450	000078-78-4	Isopentane	
62640	008001-39-6	Japan wax	
62720	001332-58-7	Kaolin	
62800	—	Kaolin, calcined	
62960	000050-21-5	Lactic acid	
63040	000138-22-7	Lactic acid, butyl ester	
63280	000143-07-7	Lauric acid	
63760	008002-43-5	Lecithin	
63840	000123-76-2	Levulinic acid	
63920	000557-59-5	Lignoceric acid	
64015	000060-33-3	Linoleic acid	
64150	028290-79-1	Linolenic acid	
64500	—	Lysine, salts	
64640	001309-42-8	Magnesium hydroxide	SML(T) = 30 mg/kg ⁽⁴⁾
64720	001309-48-4	Magnesium oxide	
64800	00110-16-7	Maleic acid	
65020	006915-15-7	Malic acid	
65040	000141-82-2	Malonic acid	
65520	000087-78-5	Mannitol	
65920	066822-60-4	N-Methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2- pyrrolidone, copolymers	
66200	037206-01-2	Methylcarboxymethylcellulose	
66240	009004-67-5	Methylcellulose	
66560	004066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg ⁽⁶⁾
66580	000077-62-3	2,2'-Methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	SML(T) = 3 mg/kg ⁽⁶⁾
66640	009004-59-5	Methylethylcellulose	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
66695	—	Methylhydroxymethylcellulose	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
66700	009004-65-3	Methylhydroxypropylcellulose	
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	
67120	012001-26-2	Mica	SML = 5 mg/kg
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	
67180	—	Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester	
67200	001317-33-5	Molybdenum disulphide	SML = 5 mg/kg (1)
67840	—	Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	
67850	008002-53-7	Montan wax	
67891	000544-63-8	Myristic acid	SML = 5 mg/kg (sum of phosphite and phosphate)
68040	003333-62-8	7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
68125	037244-96-5	Nepheline syenite	
68145	080410-33-9	2,2',2''-Nitrilo(triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite)	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
68960	000301-02-0	Oleamide	
69040	000112-80-1	Oleic acid	
69760	000143-28-2	Oleyl alcohol	SML = 0,05 mg/kg
70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
70240	012198-93-5	Ozokerite	
70400	000057-10-3	Palmitic acid	SML = 0,05 mg/kg
71020	000373-49-9	Palmitoleic acid	
71440	009000-69-5	Pectin	
71600	000115-77-5	Pentaerythritol	SML = ND (DL = 0,02 mg/kg, analytical tolerances included)
71635	025151-96-6	Pentaerythritol dioleate	
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	SML = 5 mg/kg (sum of phosphite and phosphate)
71720	000109-66-0	Pentane	
72640	007664-38-2	Phosphoric acid	
73160	—	Phosphoric acid, mono- and di-n-alkyl (C ₁₆ and C ₁₈) esters	SML = ND (DL = 0,02 mg/kg, analytical tolerances included)
73720	000115-96-8	Phosphoric acid, trichloroethyl ester	
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	SML = 5 mg/kg (sum of phosphite and phosphate)
74480	000088-99-3	o-Phthalic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
76320	000085-44-9	Phthalic anhydride	In compliance with the specifications laid down in Annex V
76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6800)	
76730	—	Polydimethylsiloxane, gamma-hydroxypropylated	
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
76960	025322-68-3	Polyethyleneglycol	SML = 0,05 mg/kg
77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil	
77702	—	Polyethyleneglycol esters of aliph. monocarb. acids (C ₆ -C ₂₂) and their ammonium and sodium sulphates	
77895	068439-49-6	Polyethyleneglycol(EO = 2-6) monoalkyl (C ₁₆ -C ₁₈) ether	
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl (C ₂ -C ₄) dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
80800	025322-69-4	Polypropyleneglycol	
81220	192268-64-7	Poly-[[[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediyl-[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidiny)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinyamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine	SML = 5 mg/kg
81515	087189-25-1	Poly(zinc glycerolate)	SML(T) = 30 mg/kg (7) (expressed as copper); SML = 48 mg/kg (expressed as iron)
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	
81840	000057-55-6	1,2-Propanediol	
81882	000067-63-0	2-Propanol	
82000	000079-09-4	Propionic acid	
82080	009005-37-2	1,2-Propyleneglycol alginate	
82240	022788-19-8	1,2-Propyleneglycol dilaurate	
82400	000105-62-4	1,2-Propyleneglycol dioleate	
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	
82720	006182-11-2	1,2-Propyleneglycol distearate	
82800	027194-74-7	1,2-Propyleneglycol monolaurate	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
82960	001330-80-9	1,2-Propyleneglycol monooleate	SML(T) = 0,18 mg/kg ⁽¹⁶⁾ (expressed as Tin)
83120	029013-28-3	1,2-Propyleneglycol monopalmitate	
83300	001323-39-3	1,2-Propyleneglycol monostearate	
83320	—	Propylhydroxyethylcellulose	
83325	—	Propylhydroxymethylcellulose	
83330	—	Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	
83610	073138-82-6	Resin acids and Rosin acids	
83840	008050-09-7	Rosin	
84000	008050-31-5	Rosin, ester with glycerol	
84080	008050-26-8	Rosin, ester with pentaerythritol	
84210	065997-06-0	Rosin, hydrogenated	
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	
84560	009006-04-6	Rubber, natural	
84640	000069-72-7	Salicylic acid	
85360	000109-43-3	Sebacic acid, dibutyl ester	
85600	—	Silicates, natural	
85610	—	Silicates, natural, silanated (with the exception of asbestos)	
85680	001343-98-2	Silicic acid	
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
86000	—	Silicic acid, silylated	
86160	000409-21-2	Silicon carbide	
86240	007631-86-9	Silicon dioxide	
86285	—	Silicon dioxide, silanated	
86560	007647-15-6	Sodium bromide	
86720	001310-73-2	Sodium hydroxide	
87040	001330-43-4	Sodium tetraborate	
87200	000110-44-1	Sorbid acid	
87280	029116-98-1	Sorbitan dioleate	
			SML(T) = 6 mg/kg ⁽²³⁾ (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p.32).

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
87520	062568-11-0	Sorbitan monobehenate	In compliance with the specifications laid down in Annex V
87600	001338-39-2	Sorbitan monolaurate	
87680	001338-43-8	Sorbitan monooleate	
87760	026266-57-9	Sorbitan monopalmitate	
87840	001338-41-6	Sorbitan monostearate	
87920	061752-68-9	Sorbitan tetrastearate	
88080	026266-58-0	Sorbitan trioleate	
88160	054140-20-4	Sorbitan tripalmitate	
88240	026658-19-5	Sorbitan tristearate	
88320	000050-70-4	Sorbitol	
88600	026836-47-5	Sorbitol monostearate	
88640	008013-07-8	Soybean oil, epoxidised	
88800	009005-25-8	Starch, edible	
88880	068412-29-3	Starch, hydrolysed	
88960	000124-26-5	Stearamide	
89040	000057-11-4	Stearic acid	
89200	007617-31-4	Stearic acid, copper salt	
89440	—	Stearic acid, esters with ethyleneglycol	
90720	058446-52-9	Stearoylbenzoylmethane	
90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	
90960	000110-15-6	Succinic acid	
91200	000126-13-6	Sucrose acetate isobutyrate	
91360	000126-14-7	Sucrose octaacetate	
91840	007704-34-9	Sulphur	
91920	007664-93-9	Sulphuric acid	
92030	010124-44-4	Sulphuric acid, copper salt	
92080	014807-96-6	Talc	
92150	001401-55-4	Tannic acids	
92160	000087-69-4	Tartaric acid	
			According to the JECFA specifications

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
92195	—	Taurine, salts	
92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	
92350	000112-60-7	Tetraethyleneglycol	
92640	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-(5.1.1.1.2)-heneicosan-21-one, polymer	SML = 5 mg/kg
92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	SML = 6 mg/kg
93440	013463-67-7	Titanium dioxide	
93520	000059-02-9 010191-41-0	alpha-Tocopherol	
93680	009000-65-1	Tragacanth gum	
93720	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
94320	000112-27-6	Triethyleneglycol	
94960	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)
95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
95855	007732-18-5	Water	In compliance with Directive 98/83/EEC
95859	—	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
95883	—	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
95905	013983-17-0	Wollastonite	
95920	—	Wood flour and fibers, untreated	
95935	011138-66-2	Xanthan gum	
96190	020427-58-1	Zinc hydroxide	
96240	001314-13-2	Zinc oxide	
96320	001314-98-3	Zinc sulphide	

Section B

Incomplete list of additives referred to in Article 4, second paragraph

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
30180	002180-18-9	Acetic acid, manganese salt	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg ⁽¹⁾
34230	—	Alkyl(C ₈ -C ₂₂)sulphonic acids	SML = 6 mg/kg
35760	001309-64-4	Antimony trioxide	SML = 0,02 mg/kg (expressed as Antimonium and analytical tolerance included)
36720	017194-00-2	Barium hydroxide	SML(T) = 1 mg/kg ⁽¹²⁾ (expressed as Barium)
36800	010022-31-8	Barium nitrate	SML(T) = 1 mg/kg ⁽¹²⁾ (expressed as Barium)
38240	000119-61-9	Benzophenone	SML = 0,6 mg/kg
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0,6 mg/kg
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	SML = 18 mg/kg
38800	032687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl) hydrazide	SML = 15 mg/kg
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML = 0,6 mg/kg
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	SML = 5 mg/kg
39090	—	N,N-Bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine	SML(T) = 1,2 mg/kg ⁽¹³⁾
39120	—	N,N-Bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine hydrochlorides	SML(T) = 1,2 mg/kg ⁽¹³⁾ expressed as Tertiary amine (expressed excluding HCl)
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30 mg/kg
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2,4 mg/kg
40800	013003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
40980	019664-95-0	Butyric acid, manganese salt	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
42000	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	SML = 30 mg/kg
42400	010377-37-4	Carbonic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
42480	000584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg
43600	004080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	SML = 0,3 mg/kg
43680	000075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Annex V
44960	011104-61-3	Cobalt oxide	SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt)
45440	—	Cresols, butylated, styrenated	SML = 12 mg/kg
45650	006197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0,05 mg/kg
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm ²
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
48640	000131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg
48880	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾
49600	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg ⁽¹⁶⁾ (expressed as Tin)
49840	002500-88-1	Diocetadecyl disulphide	SML = 3 mg/kg
50160	—	Di-n-octyltin bis(n-alkyl(C ₁₀ -C ₁₆) mercapto acetate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50240	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50360	—	Di-n-octyltin bis(ethyl maleate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50400	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50480	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50560	—	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50640	003648-18-8	Di-n-octyltin dilaurate	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50720	015571-60-5	Di-n-octyltin dimaleate	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50800	—	Di-n-octyltin dimaleate, esterified	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50880	—	Di-n-octyltin dimaleate, polymers (N = 2-4)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
50960	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
51040	015535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
51120	—	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	SML(T) = 0,04 mg/kg ⁽¹⁷⁾ (expressed as Tin)
51570	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg ⁽²⁵⁾
51680	000102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg
52000	027176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52320	052047-59-3	2-(4-Dodecylphenyl)indole	SML = 0,06 mg/kg
52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3,6 mg/kg
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
58960	000057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
59120	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	SML = 45 mg/kg
59200	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 6 mg/kg
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	SML = 1,5 mg/kg
60400	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg ⁽¹⁹⁾
60800	065447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl)benzotriazole	SML(T) = 30 mg/kg ⁽¹⁹⁾
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁵⁾
63200	051877-53-3	Lactic acid, manganese salt	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
64320	010377-51-2	Lithium iodide	SML(T) = 1 mg/kg ⁽¹¹⁾ (expressed as Iodine) and SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
65120	007773-01-5	Manganese chloride	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
65200	012626-88-9	Manganese hydroxide	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
65280	010043-84-2	Manganese hypophosphite	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
65360	011129-60-5	Manganese oxide	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
65440	—	Manganese pyrophosphite	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)
66360	085209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	SML = 5 mg/kg
66400	000088-24-4	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg ⁽²⁰⁾
66480	000119-47-1	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg ⁽²⁰⁾
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24 mg/kg
67520	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg ⁽¹⁶⁾ (expressed as Tin)
67600	—	Mono-n-octyltin tris(alkyl(C ₁₀ -C ₁₆) mercaptoacetate)	SML(T) = 1,2 mg/kg ⁽¹⁸⁾ (expressed as Tin)
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1,2 mg/kg ⁽¹⁸⁾ (expressed as Tin)
67760	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1,2 mg/kg ⁽¹⁸⁾ (expressed as Tin)
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.
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
68400	010094-45-8	Octadecylceramide	SML = 5 mg/kg
68860	004724-48-5	n-Octylphosphonic acid	SML = 0,05 mg/kg
69840	016260-09-6	Oleypalmitamide	SML = 5 mg/kg
72160	000948-65-2	2-Phenylindole	SML = 15 mg/kg
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2,4 mg/kg
73040	013763-32-1	Phosphoric acid, lithium salts	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
73120	010124-54-6	Phosphoric acid, manganese salt	SML(T) = 0,6 mg/kg ⁽¹⁰⁾ (expressed as Manganese)

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
74400	—	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	SML = 30 mg/kg
77440	—	Polyethyleneglycol diricinoleate	SML = 42 mg/kg
77520	061791-12-6	Polyethyleneglycol ester of castor oil	SML = 42 mg/kg
78320	009004-97-1	Polyethyleneglycol monoricinoleate	SML = 42 mg/kg
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	SML = 3 mg/kg
81680	007681-11-0	Potassium iodide	SML(T) = 1 mg/kg ⁽¹¹⁾ (expressed as Iodine)
82020	019019-51-3	Propionic acid, cobalt salt	SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt)
83595	119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	SML = 18 mg/kg and in compliance with the specifications mentioned in Annex V.
83700	000141-22-0	Ricinoleic acid	SML = 42 mg/kg
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
84880	000119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
85760	012068-40-5	Silicic acid, lithium aluminium salt(2:1:1)	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
85920	012627-14-4	Silicic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as Lithium)
86800	007681-82-5	Sodium iodide	SML(T) = 1 mg/kg ⁽¹¹⁾ (expressed as Iodine)
86880	—	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9 mg/kg
89170	013586-84-0	Stearic acid, cobalt salt	SML(T) = 0,05 mg/kg ⁽¹⁴⁾ (expressed as Cobalt)
92000	007727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg ⁽¹²⁾ (expressed as Barium)
92320	—	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid	SML = 15 mg/kg
92560	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	SML = 18 mg/kg
92800	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	SML = 0,48 mg/kg
92880	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	SML = 2,4 mg/kg
93120	000123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg ⁽²¹⁾
93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg ⁽²¹⁾
94560	000122-20-3	Triisopropanolamine	SML = 5 mg/kg
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 6 mg/kg
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 5 mg/kg
95600	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	SML = 5 mg/kg

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer	SML = 0,05 mg/kg for Crotonic acid (as impurity) and in compliance with the specifications laid down in Annex V

ANNEX V

SPECIFICATIONS

Part A: General specifications

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0,02 mg/kg of food or food simulant, analytical tolerance included). However, the migration value of the primary aromatic amines listed in this Directive are excluded from this restriction.

Part B: Other specifications

Ref. No	OTHER SPECIFICATIONS
16690	Divinylbenzene It may contain up to 40 % of Ethylvinylbenzene.
18888	<p>3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer</p> <p>Definition</p> <p>The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> cepa 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</p> <p>Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)</p> <p>CAS number</p> <p>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-CH-CH}_2\text{-C-)}_m & \text{- (O-CH-CH}_2\text{-C-)}_n \end{array} $ <p>where $n/(m + n)$ greater than 0 and less or equal to 0,25</p> <p>Average molecular weight</p> <p>Not less than 150 000 Daltons (measured by gel permeation chromatography).</p> <p>Assay</p> <p>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</p> <p>White to off-white powder after isolation</p> <p>Characteristics</p> <p>Identification tests:</p> <p>Solubility</p> <p>Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.</p> <p>Migration</p> <p>The migration of crotonic acid should not exceed 0,05 mg/kg food.</p> <p>Purity</p> <p>Prior to granulation the raw material copolymer powder must contain:</p> <p>— Nitrogen</p> <p>Not more than 2 500 mg/kg of plastic</p> <p>— Zinc</p> <p>Not more than 100 mg/kg of plastic</p> <p>— Copper</p> <p>Not more than 5 mg/kg of plastic</p>

Ref. No	OTHER SPECIFICATIONS
	<ul style="list-style-type: none"> — 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
23547	Polydimethylsiloxane (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (= 100 centistokes) at 25 °C
25385	Triallylamine 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.
38320	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl) stilbene Not more than 0,05 %w/w (quantity of substance used/quantity of the formulation)
43680	Chlorodifluoromethane Content of chlorofluoromethane less than 1 mg/kg of the substance
47210	Dibutylthiostannoic acid polymer Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)
76721	Polydimethylsiloxane (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (= 100 centistokes) at 25 °C
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 phosphorous 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 (*)), — 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(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(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS.No 112949-97-0) (< 5 % w/w (*)). <p>Other specifications:</p> <ul style="list-style-type: none"> — Phosphor content of min. 5,4 % to max. 5,9 % — Acid value of max. 10 mg KOH per gram — Melt range of 85-110 °C
88640	Soybean oil, epoxidized Oxirane < 8 %, iodine number < 6
95859	<p>Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks</p> <p>The product should 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 11×10^{-6} m²/s (= 11 centistokes) at 100 °C — Average molecular weight not less than 500.
95883	<p>White mineral oils, paraffinic derived from petroleum based hydrocarbon feedstocks</p> <p>The product should 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 $8,5 \times 10^{-6}$ m²/s (= 8,5 centistokes) at 100 °C — Average molecular weight not less than 480

(*) Quantity of substance used /quantity of formulation

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 Ref. Nos: 10060 and 23920.
- (³) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. 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 Ref. 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 Ref. 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 Ref. Nos: 66560 and 66580.
- (⁷) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. 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 Ref. Nos: 42400, 64320, 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 Ref. 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 of the following substances mentioned as Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. 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 Ref. Nos: 17260 and 18670.
- (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 Ref. 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 Ref. 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 Ref. 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 Ref. Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

ANNEX VII

Part A

REPEALED DIRECTIVE AND ITS AMENDMENTS

(Referred to by Article 10(1))

Commission Directive 90/128/EEC (OJ L 349, 13.12.1990, p. 26)

Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p. 21)

Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p. 26)

Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p. 44)

Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p. 26)

Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p. 41)

Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p. 18)

Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p. 19)

Part B

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

(Referred to by Article 10(1))

Directive	Deadlines		
	For transposition	To permit trade in those products which comply with this Directive	To prohibit trade in those products which do not comply with this Directive
90/128/EEC (OJ L 349, 13.12.1990, p. 26)	31 December 1990	1 January 1991	1 January 1993
92/39/EEC (OJ L 168, 23.6.1992, p. 21)	31 December 1992	31 March 1994	1 April 1995
93/9/EEC (OJ L 90, 14.4.1993, p. 26)	1 April 1994	1 April 1994	1 April 1996
95/3/EC (OJ L 41, 23.2.1995, p. 44)	1 April 1996	1 April 1996	1 April 1998
96/11/EC (OJ L 61, 12.3.1996, p. 26)	1 January 1997	1 January 1997	1 January 1999
1999/91/EC (OJ L 310, 4.12.1999, p. 41)	31 December 2000	1 January 2002	1 January 2003
2001/62/EC (OJ L 221, 17.8.2001, p. 18)	30 November 2002	1 December 2002	1 December 2002
2002/17/EC (OJ L 58, 28.2.2002, p. 19)	28 February 2003	1 March 2003	1 March 2004 1 March 2003 for materials and articles which contain Divinylbenzene

ANNEX VIII

CORRELATION TABLE

Directive 90/128/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 3a	Article 4
Article 3b	Article 5
Article 3c	Article 6
Article 4	Article 7
Article 5	Article 8
Article 6	Article 9
-	Article 10
-	Article 11
-	Article 12
ANNEX I	ANNEX I
ANNEX II	ANNEX II
ANNEX III	ANNEX III
ANNEX IV	ANNEX IV
ANNEX V	ANNEX V
ANNEX VI	ANNEX VI
-	ANNEX VII
-	ANNEX VIII