►B ►C1 **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) ◄

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►M3	Commission Directive 2005/79/EC of 18 November 2005	L 302	35	19.11.2005
►M4	Commission Directive 2007/19/EC of 30 March 2007	L 91	17	31.3.2007
►M5	Commission Directive 2008/39/EC of 6 March 2008	L 63	6	7.3.2008

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►C1	Corrigendum, OJ L 39, 13.2.2003, p. 1 (2002/72/EC)
►C2	Corrigendum, OJ L 97, 12.4.2007, p. 50 (2007/19/EC)

▼B
▼C1

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.

([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).

▼C1

(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 ([1]) 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.

(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 ([2]) 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 ([3]) and 81/432/EEC ([4]) 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 ([5]) 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.

([1]) OJ L 372, 31.12.1985, p. 14.
([2]) OJ L 44, 15.2.1978, p. 15.
([3]) OJ L 213, 16.8.1980, p. 42.
([4]) OJ L 167, 24.6.1981, p. 6.
([5]) OJ L 151, 19.6.1980, p. 21.

▼C1

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.

▼M4

▼C2

2. This Directive shall apply to the following materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose (hereafter referred to as 'plastic materials and articles'):

(a) materials and articles and parts thereof consisting exclusively of plastics;

(b) plastic multi-layer materials and articles;

(c) plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.

▼C1

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 ([1]);

(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.

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

▼M4

▼C2

4. Without prejudice to paragraph 2(c), this Directive shall not apply 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 1a

For the purpose of this Directive the following definitions shall apply:

(a) 'plastic multi-layer material or article' means a plastic material or article composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by other means;

(b) 'plastic functional barrier' means a barrier consisting of one or more layers of plastics which ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([1]) and with this Directive;

(c) 'non-fatty foods' means foods for which in migration testing simulants other than simulant D are laid down in Directive 85/572/EEC.

Article 2

1. Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 60 milligrams of the constituents released per kilogram of foodstuff or food simulant (mg/kg) (overall migration limit).

However, this limit shall be 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) in the case of the following:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 millilitres (ml) or more than 10 litres (l);

(b) sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

2. For plastic materials and articles intended to be brought into contact with or already in contact with food intended for infants and young children, as defined by Commission Directives 91/321/EEC ([2]) and 96/5/EC ([3]), the overall migration limit shall always be 60 mg/kg.

▼C1

Article 3

▼M2

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

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

▼C1

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

([1]) OJ L 338, 13.11.2004, p. 4.
([2]) OJ L 175, 4.7.1991, p. 35.
([3]) OJ L 49, 28.2.1996, p. 17.

▼C1

— 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.

▼M2

Article 4

▼M5

1. A Community 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.

Until 31 December 2009, additives which are not included in the Community list of additives may continue to be used subject to national law.

As from 1 January 2010, only additives included in the Community list of additives may be used for the manufacture of plastic materials and articles (positive list).

▼M2

2. For the additives listed in Annex III, section B, the verification of compliance with the specific migration limits in simulant D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC and Article 1 of Directive 85/572/EEC shall apply from ►M4 ►C2 1 May 2008 ◄ ◄.

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

(a) additives used only in the manufacture of:

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

— epoxy resins,

— adhesives and adhesion promoters,

— printing inks;

(b) colorants;

(c) solvents.

Article 4a

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

▼M2

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

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

▼M5

3. A provisional list of additives that are under evaluation by the Authority shall be made public by the Commission by 11 April 2008 at the latest. It shall be kept updated.

4. By derogation from the third subparagraph of Article 4(1), additives not included in the Community list referred to in that Article may continue to be used subject to national law after 1 January 2010 for as long as they are included in the provisional list.

▼M2

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

(a) the additive must be permitted in one or more of the Member States no later than 31 December 2006;

(b) the data referred to in paragraph 2 concerning that additive must have been supplied in accordance with the Authority requirements no later than 31 December 2006.

▼M5

6. An additive shall be removed from the provisional list:

(a) when it is included in the Community list of additives; or

(b) when a decision is taken by the Commission not to include it in the Community list of additives; or

(c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

▼M2

Article 4b

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

▼M4
▼C2

Article 4c

For the use of additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c), the following rules shall apply:

(a) for the additives listed in Annex III, the restrictions and/or specifications on their use set out in that Annex shall apply, without prejudice to Article 4(2);

(b) by way of derogation from Article 4(1) and Article 4a(1) and (5), additives not listed in Annex III may continue to be used, until further review, subject to national law;

(c) by way of derogation from Article 4b Member States may continue to authorise additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c) at national level.

▼C2

Article 4d

For the use of additives exclusively acting as polymerisation production aids which are not intended to remain in the finished article (hereinafter PPAs), for the manufacture of plastic materials and articles, the following rules shall apply:

(a) for the PPAs listed in Annex III, the restrictions and/or specifications on their use set out in Annex III shall apply, without prejudice to Article 4(2);

(b) by way of derogation from Article 4(1) and Article 4a(1) and (5), the PPAs not listed in Annex III may continue to be used, until further review, subject to national law;

(c) by way of derogation from Article 4b, Member States may continue to authorise PPAs at national level.

Article 4e

The use of azodicarbonamide, Ref. No 36640 (CAS No 000123-77-3) in the manufacture of plastic materials and articles is prohibited.

▼C1

Article 5

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

▼M2

Article 5a

1. Additives referred to in Article 4, which are authorised as food additives by Council Directive 89/107/EEC [1] or flavourings by Council Directive 88/388/EEC [2] shall not migrate into:

(a) foodstuffs in quantities having a technological function in the final foodstuffs;

(b) foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in Article 4 of this Directive, whichever is the lower;

(c) foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in Article 4 of this Directive.

▼M4

▼C2

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

▼M2

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

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[1] OJ L 40, 11.2.1989, p. 27.
[2] OJ L 184, 15.7.1988, p. 61.

▼C1

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.

▼M2

Article 7

The specific migration limits in the list set out in Annexes II and III are expressed in mg/kg. However, such limits are expressed in mg/dm^2 in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;

(b) sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in Annexes II and III, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm^2.

▼M4

▼C2

For plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 91/321/EEC and 96/5/EC, the SMLs shall always be applied as mg/kg.

Article 7a

1. In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Directive.

2. By way of derogation from paragraph 1, a layer which is not in direct contact with food and is separated from the food by a plastic functional barrier, may, provided that the finished material or article complies with the specific and overall migration limits specified in this Directive:

(a) not comply with the restrictions and specifications set in this Directive,

(b) be manufactured with substances other than those included in this Directive or in the national lists concerning the plastic materials and articles intended to come into contact with food.

3. The migration of the substances referred to in paragraph 2(b) into food or simulant shall not exceed 0,01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council ([1]). This limit shall always be expressed as concentration in foods or simulants. It shall apply to a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

4. The substances referred to in paragraph 2(b) shall not belong to either of the following categories:

([1]) OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.

▼C2

(a) substances classified as proved or suspect 'carcinogenic', 'mutagenic' or 'toxic to reproduction' substances in Annex I to Council Directive 67/548/EEC [1];

(b) substances classified under the self-responsibility criteria as 'carcinogenic', 'mutagenic' or 'toxic to reproduction' according to the rules of Annex VI to Directive 67/548/EEC.

▼C1

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.

▼M2

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

▼C1

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.

▼M4

▼C2

5. Notwithstanding paragraph 1, for phthalates (Ref. No 74640, 74880, 74560, 75100, 75105) referred to in Annex III Section B, the verification of the SML shall only be performed in food simulants. However, verification of the SML may be performed in food where the food has not already been in contact with the material or article and is pre-tested for the phthalate and the level is not statistically significant or greater than or equal to the limit of quantification.

Article 9

1. At the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

2. The declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex VIa.

3. Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Directive shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other

[1] OJ 196, 16.8.1967, p. 1.

▼C2

analysis, and evidence on the safety or reasoning demonstrating compliance.

▼C1

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.

▼C1

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 be 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:

$$M = \frac{m \cdot a_2}{a_1 \cdot q} \cdot 1000$$

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 dm^2 of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm^2 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.

▼M4

▼C2

2a. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF):

'Fat Reduction Factor' (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or simulant D and its substitutes shall be divided before comparison with the specific migration limits.

General rules

Substances considered 'lipophilic' for the application of the FRF are listed in Annex IVa. The specific migration of lipophilic substances in mg/kg (M) shall be corrected by the FRF variable between 1 and 5 (M_{FRF}). The following equations shall be applied before comparison with the legal limit:

$M_{FRF} = M/FRF$

and

FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100

This correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food containing less than 20 % fat;

(b) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 91/321/EEC and 96/5/EC;

(c) for substances in the Community lists in Annexes II and III having a restriction in column (4) SML= ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg;

▼C2

(d) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

This correction by the FRF is applicable under certain conditions in the following case:

For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more than 20 % fat, either the migration is calculated as concentration in the food or food simulant (mg/kg) and corrected by the FRF, or it is re-calculated as mg/dm^2 without applying the FRF. If one of the two values is below the SML, the material or article shall be considered in compliance.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

2b. Correction of specific migration in food simulant D:

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

(a) the reduction factor referred to in point 3 of the Annex to Directive 85/572/EEC, hereinafter termed simulant D Reduction Factor (DRF).

The DRF may not be applicable when the specific migration into simulant D is higher than 80 % of the content of the substance in the finished material or article (for example thin films). Scientific or experimental evidence (for example testing with the most critical foods) is required to determine whether the DRF is applicable. It is also not applicable for substances in the Community lists having a restriction in column (4) SML = ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg.

(b) the FRF is applicable to migration into simulants, provided the fat content of the food to be packed is known and the requirements mentioned in point 2a are fulfilled.

(c) the Total Reduction Factor (TRF) is the factor, with a maximum value of 5, by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the legal limit. It is obtained by multiplying the DRF by the FRF, when both factors are applicable.

▼C1

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.

▼C1

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.

▼M4

▼C2

5a. Caps, lids, gaskets, stoppers and similar sealing articles:

(a) If the intended use is known, such articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use. It is assumed that these articles are in contact with a quantity of food filling the container. The results shall be expressed in mg/kg or mg/dm^2 in accordance to the rules of Articles 2 and 7 taking into account the whole contact surface of sealing article and container.

(b) If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result be expressed in mg/article. The value obtained shall be added, if appropriate, to the quantity migrated from the container for which it is intended to be used.

▼C1

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 $M_3 - M_2$ does 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/dm^2 in migration tests using rectified olive oil or substitutes,

— 12 mg/kg or 2 mg/dm^2 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.

▼C1

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/dm^2, according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit.

▼C1

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 macromolecular substances.

▼M3

2. The following substances are not included even if they are intentionally used and are authorised:

   (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing '… acid(s), salts' appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

   (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:

      (i) substances whose name contains '… acid(s), salts' which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,

      (ii) substances referred to in note 38 of Annex VI.

▼C1

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),

▼C1

— 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 dm^2 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;

▼M2

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

▼C1

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 dm^2 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 dm^2 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;

▼C1

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.

▼C1

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	
▼M2			
10599/90A	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, distilled	QMA(T) = 0,05 mg/6 dm^2 ([27])
10599/91	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, non distilled	QMA(T) = 0,05 mg/6 dm^2 ([27])
10599/92A	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	QMA(T) = 0,05 mg/6 dm^2 ([27])
10599/93	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, non distilled	QMA(T) = 0,05 mg/6 dm^2 ([27])
▼C1			
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	►M3 SML(T) = 6 mg/kg ([36]) ◄
10750	002495-35-4	Acrylic acid, benzyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
10780	000141-32-2	Acrylic acid, n-butyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
10810	002998-08-5	Acrylic acid, sec-butyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
10840	001663-39-4	Acrylic acid, tert-butyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
▼M3			
11005	012542-30-2	Acrylic acid, dicyclopentenyl ester	QMA = 0,05 mg/6 dm^2
▼C1			
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg ([1])
11470	000140-88-5	Acrylic acid, ethyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
▼M3			
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	SML = 0,05 mg/kg
▼C1			
11510	000818-61-1	Acrylic acid, hydroxyethyl ester	See ‘Acrylic acid, monoester with ethyleneglycol’

▼C1

(1)	(2)	(3)	(4)
11530	►M2 00999-61-1 ◄	Acrylic acid, 2-hydroxypropyl ester	►M2 QMA = 0,05 mg/6 dm^2 for the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Annex V ◄
11590	000106-63-8	Acrylic acid, isobutyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
11680	000689-12-3	Acrylic acid, isopropyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
11710	000096-33-3	Acrylic acid, methyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	►M3 SML(T) = 6 mg/kg ([36]) ◄
11890	002499-59-4	Acrylic acid, n-octyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
11980	000925-60-0	Acrylic acid, propyl ester	►M3 SML(T) = 6 mg/kg ([36]) ◄
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

▼M3

12786	000919-30-2	3-Aminopropyltriethoxysilane	►M4 ►C2 Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers and SML = 0,05 mg/kg when used for the surface treatment of materials and articles. ◄ ◄

▼C1

12788	002432-99-7	11-Aminoundecanoic acid	SML= 5 mg/kg
12789	007664-41-7	Ammonia	

▼C1

(1)	(2)	(3)	(4)
12820	000123-99-9	Azelaic acid	
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
▼M3			
13317	132459-54-2	N,N′-Bis[4-(ethoxycarbonyl) phenyl]-1,4,5,8-naphthalenetetracarboxydiimide	SML = 0,05 mg/kg. Purity > 98,1 % (w/w). To be used only as co-monomer (max 4 %) for polyesters (PET, PBT)
▼M2			
13323	000102-40-9	1,3-Bis(2-hydroxyethoxy) benzene	SML = 0,05 mg/kg
▼C1			
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	►M2 SML(T) = 0,6 mg/kg ([28]) ◄
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)'

▼C1

(1)	(2)	(3)	(4)
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	►M3 SML(T) = 5 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	
13932	000598-32-3	3-Buten-2-ol	QMA = ND (DL = 0,02 mg/6 dm^2) To be used only as a comonomer for the preparation of polymeric 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)

▼M3

14260	000502-44-3	Caprolactone	SML = 0,05 mg/kg (expressed as the sum of caprolactone and 6-hydroxyhexanoic acid)

▼C1

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	

▼C1

(1)	(2)	(3)	(4)
14710	000108-39-4	*m*-Cresol	
14740	000095-48-7	*o*-Cresol	
14770	000106-44-5	*p*-Cresol	
▼M2			
14800	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm^2 ([33])
▼C1			
14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
14880	000105-08-8	1,4-Cyclohexanedimethanol	See '1,4-Bis(hydroxymethyl) cyclohexane'
14950	003173-53-3	Cyclohexyl isocyanate	►M2 QM(T) = 1 mg/kg in FP (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	
▼M4			
▼C2			
15267	000080-08-0	4,4′-Diaminodiphenyl sulphone	SML = 5 mg/kg
▼C1			
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
▼M2			
▼M5			
15404	000652-67-5	1,4:3,6-Dianhydrosorbitol	SML = 5 mg/kg. Only for use as a co-monomer in poly(ethylene-co-isosorbide terephthalate)
▼C1			
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15610	000080-07-9	4,4′-Dichlorodiphenyl sulphone	SML = 0,05 mg/kg
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′-Difluorobenzophenone	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

▼C1

(1)	(2)	(3)	(4)
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
▼M2			
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0,05 mg/kg ([32]). To be used only in polyamides.
▼C1			
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	►M4 ►C2 SML = 5 mg/kg ◄ ◄
16480	000126-58-9	Dipentaerythritol	
▼M2			
16540	000102-09-0	Diphenyl carbonate	SML = 0,05 mg/kg
▼C1			
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	
▼M3			
16955	000096-49-1	Ethylene carbonate	Residual content = 5 mg/kg of hydrogel at a maximum ratio of 10 g of hydrogel to 1 kg of food. The hydrolysate contains ethyleneglycol having an SML = 30 mg/kg
▼C1			
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg ([3])

▼C1

(1)	(2)	(3)	(4)
17005	000151-56-4	Ethyleneneimine	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
▼M2			
17110	016219-75-3	5-Ethylidenebicyclo[2,2,1] hept-2-ene	QMA = 0,05 mg/6 dm^2. The ratio surface/quantity of food shall be lower than 2 dm^2/kg
▼C1			
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	SML(T) = 15 mg/kg ([22])
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	
18430	000116-15-4	Hexafluoropropylene	SML = ND (DL = 0,01 mg/kg)
18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/kg
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)
▼M2			
18700	000629-11-8	1,6-Hexanediol	SML = 0,05 mg/kg
▼C1			
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	
▼M2			
18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0,05 mg/kg
▼C1			
18897	016712-64-4	6-Hydroxy-2-naphthalenecarboxylic acid	SML = 0,05 mg/kg

▼C1

(1)	(2)	(3)	(4)
18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	►M2 SML = 0,05 mg/kg ◄
19000	000115-11-7	Isobutene	
19060	000109-53-5	Isobutyl vinyl ether	QM = 5 mg/kg in FP
19110	004098-71-9	1-Isocyanato-3-isocyanato-methyl-3,5,5-trimethylcyclo-hexane	QM(T) = 1 mg/kg (expressed as NCO) ([26])
▼M5			
19150	000121-91-5	Isophthalic acid	SML(T) = 5 mg/kg (43)
19180	000099-63-8	Isophthalic acid dichloride	SML(T) = 5 mg/kg (43) (expressed as isophthalic acid)
▼C1			
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	
19460	000050-21-5	Lactic acid	
19470	000143-07-7	Lauric acid	
19480	002146-71-6	Lauric acid, vinyl ester	
19490	000947-04-6	Laurolactam	SML = 5 mg/kg
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg ([4])
19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg ([4]) (expressed as maleic acid)
19975	000108-78-1	Melamine	See '2,4,6-triamino-1,3,5-triazine'
19990	000079-39-0	Methacrylamide	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20020	000079-41-4	Methacrylic acid	►M3 SML(T) = 6 mg/kg ([37]) ◄
20050	000096-05-9	Methacrylic acid, allyl ester	SML = 0,05 mg/kg
20080	002495-37-6	Methacrylic acid, benzyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
20110	000097-88-1	Methacrylic acid, butyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
20140	002998-18-7	Methacrylic acid, sec-butyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
20170	000585-07-9	Methacrylic acid, tert-butyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
20260	000101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0,05 mg/kg
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0,05 mg/kg
▼M2			
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	SML = 0,05 mg/kg
▼C1			
20530	002867-47-2	Methacrylic acid, 2-(dimethy-lamino)-ethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)

▼C1

(1)	(2)	(3)	(4)
20590	000106-91-2	Methacrylic acid, 2,3-epoxy-propyl ester	QMA = 0,02 mg/6 dm^2
20890	000097-63-2	Methacrylic acid, ethyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
21010	000097-86-9	Methacrylic acid, isobutyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
21100	004655-34-9	Methacrylic acid, isopropyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
21130	000080-62-6	Methacrylic acid, methyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	►M3 SML(T) = 6 mg/kg ([37]) ◄
21280	002177-70-0	Methacrylic acid, phenyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
21340	002210-28-8	Methacrylic acid, propyl ester	►M3 SML(T) = 6 mg/kg ([37]) ◄
▼M3			
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	QMA = ND (DL = 0,02 mg/6 dm^2)
▼M2			
21400	054276-35-6	Methacrylic acid, sulpho-propyl ester	QMA = 0,05 mg/6 dm^2
▼C1			
21460	000760-93-0	Methacrylic anhydride	►M3 SML(T) = 6 mg/kg ([37]) ◄
21490	000126-98-7	Methacrylonitrile	SML = ND (DL = 0,020 mg/kg, analytical tolerance included)
21520	001561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
21550	000067-56-1	Methanol	
21640	000078-79-5	2-Methyl-1,3-butadiene	QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
21730	000563-45-1	3-Methyl-1-butene	QMA = 0,006 mg/6 dm^2. For use only in Polypropylene
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)
▼M4			
▼C2			
21970	000923-02-4	N-Methylolmethacrylamide	SML = 0,05 mg/kg
▼C1			
22150	000691-37-2	4-Methyl-1-pentene	►M2 SML = 0,05 mg/kg ◄
▼M3			
22210	000098-83-9	alpha-Methylstyrene	SML = 0,05 mg/kg
▼C1			
22331	025513-64-8	►M2 Mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane ◄	QMA = 5 mg/6 dm^2

▼C1

(1)	(2)	(3)	(4)
22332	►M2 — ◄	Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diiso-cyanate 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	
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5 mg/kg
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-propa-nediol'
22450	009004-70-0	Nitrocellulose	
22480	000143-08-8	1-Nonanol	
22550	000498-66-8	Norbornene	See 'Bicyclo[2.2.1]hept-2-ene'
22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
22600	000111-87-5	1-Octanol	
22660	000111-66-0	1-Octene	SML = 15 mg/kg
22763	000112-80-1	Oleic acid	

▼M2

22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ([29])

▼C1

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	
22900	000109-67-1	1-Pentene	SML = 5 mg/kg

▼M3

22932	001187-93-5	Perfluoromethyl perfluor-ovinyl ether	SML = 0,05 mg/kg. Only to be used for anti-stick coatings

▼C1

22937	001623-05-8	Perfluoropropylperfluorovinyl ether	SML = 0,05 mg/kg
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)

▼M2

23070	000102-39-6	(1,3-Phenylenedioxy)diacetic acid	QMA = 0,05 mg/6 dm^2

▼C1

23155	000075-44-5	Phosgene	See 'Carbonyl chloride'
23170	007664-38-2	Phosphoric acid	
23175	000122-52-1	Phosphorous acid, triethyl ester	QM = ND (DL = 1 mg/kg in FP)
23187		Phthalic acid	See 'Terephthalic acid'

▼C1

(1)	(2)	(3)	(4)
23200	000088-99-3	o-Phthalic acid	
23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg)
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	
23500	000127-91-3	beta-Pinene	
23547	009016-00-6	Polydimethylsiloxane (Mw > 6 800)	In compliance with the specifications laid down in Annex V
23590	025322-68-3	Polyethyleneglycol	
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	
23890	000079-09-4	Propionic acid	
23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg ([2]) (expressed as Acetaldehyde)
23950	000123-62-6	Propionic anhydride	
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP
24051	000120-80-9	Pyrocatechol	See ‘1,2-Dihydroxybenzene’
24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as Pyromellitic acid)
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 dm^2. 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.
24100	008050-09-7	Rosin	
24130	008050-09-7	Rosin gum	See ‘Rosin’
24160	008052-10-6	Rosin tall oil	
24190	►M3 008050-09-7 ◄	Rosin wood	►M3 See ‘Rosin’ (Reference No 24100) ◄
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	

▼C1

(1)	(2)	(3)	(4)
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	
24850	000108-30-5	Succinic anhydride	
24880	000057-50-1	Sucrose	
▼M4			
▼C2			
24886	046728-75-0	5-Sulphoisophthalic acid, monolithium salt	SML = 5 mg/kg and for lithium
▼C1			
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 5 mg/kg
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg
▼M3			
24903	068425-17-2	Syrups, hydrolysed starch, hydrogenated	In compliance with the specifications laid down in Annex V
▼C1			
24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
24940	000100-20-9	Terephthalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as Terephthalic acid)
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25080	001120-36-1	1-Tetradecene	SML = 0,05 mg/kg
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg
25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
25180	000102-60-3	N,N,N′,N′,-Tetrakis(2-hydroxypropyl)ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)
25380	—	Trialkyl acetic acid (C7-C17), vinyl esters (= Vinyl versatate)	QMA = 0,05 mg/6 dm^2
25385	000102-70-5	Triallyamine	In compliance with the specifications laid down in Annex V
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
25450	026896-48-0	Tricyclodecanedimethanol	SML = 0,05 mg/kg

▼C1

(1)	(2)	(3)	(4)
25510	000112-27-6	Triethyleneglycol	
▼M3			
25540	000528-44-9	Trimellitic acid	SML(T) = 5 mg/kg ([35])
25550	000552-30-7	Trimellitic anhydride	SML(T) = 5 mg/kg ([35]) (expressed as trimellitic acid)
▼C1			
25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	SML = 0,05 mg/kg
25900	000110-88-3	Trioxane	►M4 ►C2 SML = 5 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
▼M5			
26305	000078-08-0	Vinyltriethoxysilane	SML = 0,05 mg/kg. Only to be used as a surface treatment agent
▼C1			
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
26360	007732-18-5	Water	In compliance with Directive 98/83/EC

▼C1

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)
▼M2			
▼M3			
▼C1			
13050	000528-44-9	1,2,4-Benzenetricarboxylic acid	See ‘Trimellitic acid’
▼M3			
▼M2			
▼C1			
15730	000077-73-6	Dicyclopentadiene	
▼M2			
▼C1			
18370	000592-45-0	1,4-Hexadiene	
▼M2			
▼M3			
▼M2			
▼M4			
▼C2			
▼M3			
▼C1			
26230	000088-12-0	Vinylpyrrolidone	

▼C1

ANNEX III

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

GENERAL INTRODUCTION

▼M2

1. This Annex contains the list of:

   (a) substances which are incorporated into plastics to achieve a technical effect in the finished product, including 'polymeric additives'. They are intended to be present in the finished articles;

   (b) substances used to provide a suitable medium in which polymerisation occurs.

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

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

   The list does not include:

   (a) the substances which directly influence the formation of polymers;

   (b) colorants;

   (c) solvents.

▼M3

2. The following substances are not included even if they are intentionally used and are authorised:

   (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing '… acid(s), salts' appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

   (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:

      (i) substances whose name contains '… acid(s), salts' which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,

      (ii) substances referred to in note 38 of Annex VI.

▼C1

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,

▼C1

— 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 dm^2 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	
30045	000123-86-4	Acetic acid, butyl ester	
30080	004180-12-5	Acetic acid, copper salt	►M3 SML(T) = 5 mg/kg (7) (expressed as Copper) ◄
30140	000141-78-6	Acetic acid, ethyl ester	
30280	000108-24-7	Acetic anhydride	
30295	000067-64-1	Acetone	
▼M5			
———			
▼C1			
30370	—	Acetylacetic acid, salts	
▼M3			
———			
30401	—	Acetylated mono- and diglycerides of fatty acids	
▼C1			
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 occuring levels are included)	
30612	—	Acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	

▼C1

(1)	(2)	(3)	(4)
30960	—	Acids, aliph., monocarb. (C_6-C_{22}), esters with polyglycerol	
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-hydroxyphenyl)ethyl)phenyl ester	SML = 5 mg/kg
▼M3			
31542	174254-23-0	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C_{16}-C_{18} alkyl esters	QM = 0,5 % (w/w) in FP
▼C1			
31730	000124-04-9	Adipic acid	
33120	—	Alcohols, aliph, monoh., sat., linear, primary (C_4-C_{24})	
33350	009005-32-7	Alginic acid	
33801	—	n-Alkyl(C_{10}-C_{13})benzenesulphonic acid	SML = 30 mg/kg
34240	—	Alkyl(C_{10}-C_{20})sulphonic acid, esters with phenols	SML = 6 mg/kg. Authorised until 1 January 2002
34281	—	Alkyl(C_8-C_{22})sulphuric acids, linear, primary with an even number of carbon atoms	
34475	—	Aluminum calcium hydroxide phosphite, hydrate	
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	
▼M2			
34850	143925-92-2	Amines, bis(hydrogenated tallow alkyl) oxidised	QM = For use only: (a) in polyolefines at 0,1 % (w/w) but not in LDPE when it is in contact with foods for which the Directive 85/572/EEC establishes a reduction factor less than 3; (b) in PETat 0,25 % (w/w) in contact with foods other of those for which the simulant D is laid down in Directive 85/572/EEC 85/572/EEC
34895	000088-68-6	2-Aminobenzamide	SML = 0,05 mg/kg. To be used only for PET for water and beverages
▼C1			
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	

▼C1

(1)	(2)	(3)	(4)
35160	006642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
35170	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
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.
35320	007664-41-7	Ammonia	
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	►M1 For use only as blowing agent. Use prohibited as from 2 August 2005. ◄
36840	012007-55-5	Barium tetraborate	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 L 330, 5.12.1998, p. 32).
36880	008012-89-3	Beeswax	
36960	003061-75-4	Behenamide	
37040	000112-85-6	Behenic acid	
37280	001302-78-9	Bentonite	
37360	000100-52-7	Benzaldehyde	In compliance with note 9 in Annex VI
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	

▼M3

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▼C1

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])

▼C1

(1)	(2)	(3)	(4)
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methyl-phenyl)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-dicumyl-phenol)).
▼M5			
38875	002162-74-5	Bis(2,6-diisopropylphenyl) carbodiimide	SML = 0,05 mg/kg. For use behind a PET layer
▼C1			
38879	135861-56-2	Bis(3,4-dimethylbenzylidene) sorbitol	
▼M4			
▼C2			
38885	002725-22-6	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxy-phenyl)-1,3,5-triazine	SML = 0,05 mg/kg. For aqueous foods only.
▼C1			
38950	079072-96-1	Bis(4-ethylbenzylidene)sorbitol	
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	SML = 1,8 mg/kg
▼M2			
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl) propane	SML(T) = 0,6 mg/kg ([28])
▼M5			
39815	182121-12-6	9,9-Bis(methoxymethyl) fluorene	SML = 0,05 mg/kg
▼C1			
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-dimethylhexane	SML = 0,05 mg/kg
40120	068951-50-8	Bis(polyethyleneglycol)hydroxymethylphosphonate	SML = 0,6 mg/kg
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	
40570	000106-97-8	Butane	
40580	000110-63-4	1,4-Butanediol	►M3 SML(T) = 5 mg/kg ([24]) ◄
41040	005743-36-2	Calcium butyrate	
41120	010043-52-4	Calcium chloride	
41280	001305-62-0	Calcium hydroxide	

▼C1

(1)	(2)	(3)	(4)
41520	001305-78-8	Calcium oxide	
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	
41680	000076-22-2	Camphor	In compliance with note 9 in Annex VI
41760	008006-44-8	Candelilla wax	
41840	000105-60-2	Caprolactam	SML(T) = 15 mg/kg ([5])
41960	000124-07-2	Caprylic acid	
▼M4			
▼C2			
42080	001333-86-4	Carbon black	In compliance with the specifications laid down in Annex V.
▼C1			
42160	000124-38-9	Carbon dioxide	
42320	007492-68-4	Carbonic acid, copper salt	►M3 SML(T) = 5 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	
▼M2			
42880	008001-79-4	Castor oil	
▼C1			
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	
▼M3			
43480	064365-11-3	►M4 ►C2 Charcoal, activated ◄ ◄	►M4 ►C2 In compliance with the specifications laid down in Annex V. ◄ ◄
▼C1			
43515	—	Chlorides of choline esters of coconut oil fatty acids	QMA = 0,9 mg/6 dm^2
44160	000077-92-9	Citric acid	
44640	000077-93-0	Citric acid, triethyl ester	
45195	007787-70-4	Copper bromide	►M3 SML(T) = 5 mg/kg ([7]) (expressed as Copper) ◄
45200	001335-23-5	►M4 ►C2 Copper iodide ◄ ◄	►M4 ►C2 SML(T) = 5 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	►M2 SML = 5 mg/kg ◄

▼C1

(1)	(2)	(3)	(4)
45560	014464-46-1	Cristobalite	
▼M2			
45600	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm^2 ([33])
45640	005232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	SML = 0,05 mg/kg
▼M5			
45703	491589-22-1	cis-1,2-Cyclohexanedicarboxylic acid, calcium salt	SML = 5 mg/kg
▼M4			
▼C2			
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	
▼C1			
45760	000108-91-8	Cyclohexylamine	
45920	009000-16-2	Dammar	
45940	000334-48-5	n-Decanoic acid	
46070	010016-20-3	alpha-Dextrin	
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	
▼M2			
46700	—	5,7-di-tert-Butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	SML = 5 mg/kg
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm^2
▼C1			
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	SML = 6 mg/kg
47210	026427-07-6	Dibutylthiostannoic acid polymer [= Thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Annex V.
47440	000461-58-5	Dicyanodiamide	
47540	027458-90-8	Di-tert-dodecyl disulphide	SML = 0,05 mg/kg
47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg ([3])

▼C1

(1)	(2)	(3)	(4)
48460	000075-37-6	1,1-Difluoroethane	
48620	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
48720	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg ([15])
▼M5			
48960	—	9,10-dihydroxy stearic acid and its oligomers	SML = 5 mg/kg
▼C1			
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	
51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	SML = 0,05 mg/kg
51760	025265-71-8 000110-98-5	Dipropyleneglycol	
52640	016389-88-1	Dolomite	
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'-Ethylenebisstearamide	
53600	000060-00-4	Ethylenediaminetetraacetic acid	
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	►M3 SML(T) = 5 mg/kg ([7]) (expressed as Copper) ◄
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	
54270	—	Ethylhydroxymethylcellulose	
54280	—	Ethylhydroxypropylcellulose	
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	SML = 6 mg/kg
54450	—	Fats and oils, from animal or vegetable food sources	
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	
55120	000110-17-8	Fumaric acid	
55190	029204-02-2	Gadoleic acid	

▼C1

(1)	(2)	(3)	(4)
55440	009000-70-8	Gelatin	
55520	—	Glass fibers	
55600	—	Glass microballs	
55680	000110-94-1	Glutaric acid	
▼M5			
55910	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates	
▼C1			
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	
▼M2			
56535	—	Glycerol, esters with nonanoic acid	
▼C1			
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
▼M2			
———————			
▼C1			
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	

▼C1

(1)	(2)	(3)	(4)
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	
▼M2			
59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg ([22]) (expressed as Formaldehyde)
▼C1			
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
▼M5			
60025	—	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene	In compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.
▼C1			
60030	012072-90-1	Hydromagnesite	
60080	012304-65-3	Hydrotalcite	
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	SML(T) = 30 mg/kg ([19])
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	

▼C1

(1)	(2)	(3)	(4)
61800	009049-76-7	Hydroxypropyl starch	
61840	000106-14-9	12-Hydroxystearic acid	
▼M4			
▼C2			
62020	007620-77-1	12-Hydroxystearic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as lithium)
▼C1			
62140	006303-21-5	Hypophosphorous acid	
62240	001332-37-2	Iron oxide	
▼M3			
62245	012751-22-3	Iron phosphide	For PET polymers and copolymers only
▼M5			
62280	009044-17-1	Isobutylene-butene copolymer	
▼C1			
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	
64720	001309-48-4	Magnesium oxide	
64800	00110-16-7	Maleic acid	SML(T) = 30 mg/kg ([4])
▼M3			
64990	025736-61-2	Maleic anhydride-styrene, copolymer, sodium salt	In compliance with specifications laid down in Annex V
▼C1			
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	

▼C1

(1)	(2)	(3)	(4)
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	
66695	—	Methylhydroxymethylcellulose	
66700	009004-65-3	Methylhydroxypropylcellulose	
▼M5			
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0,5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself.
▼M3			
66905	000872-50-4	N-Methylpyrrolidone	
66930	068554-70-1	Methylsilsesquioxane	Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane
▼C1			
67120	012001-26-2	Mica	
▼M3			
67155	—	Mixture of 4-(2-Benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl) stilbene, 4,4′-bis(2-benzoxazolyl) stilbene and 4,4′-bis(5-methyl-2-benzoxazolyl) stilbene)	Not more than 0,05 % w/w (quantity of substance used/quantity of the formulation). In compliance with the specifications laid down in Annex V
▼M2			
———————			
▼M4			
▼C2			
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.	SML = 5 mg/kg ([1])
▼C1			
67200	001317-33-5	Molybdenum disulphide	
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	

▼C1

(1)	(2)	(3)	(4)
68040	003333-62-8	7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
▼M2			
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.
▼C1			
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'-biphenyl-2,2'-diyl)phosphite)	SML =5 mg/kg (sum of phosphite and phosphate)
68960	000301-02-0	Oleamide	
69040	000112-80-1	Oleic acid	
69760	000143-28-2	Oleyl alcohol	
▼M2			
69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ([29])
▼C1			
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	
▼M5			
70480	000111-06-8	Palmitic acid, butyl ester	
▼C1			
71020	000373-49-9	Palmitoleic acid	
71440	009000-69-5	Pectin	
71600	000115-77-5	Pentaerythritol	
71635	025151-96-6	Pentaerythritol dioleate	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML = 0,05 mg/kg
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
71720	000109-66-0	Pentane	
▼M4			
▼C2			
71960	003825-26-1	Perfluorooctanoic acid, ammonium salt	Only to be used in repeated use articles, sintered at high temperatures.
▼C1			
72640	007664-38-2	Phosphoric acid	

▼C1

(1)	(2)	(3)	(4)
73160	—	Phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters	SML = 0,05 mg/kg
73720	000115-96-8	Phosphoric acid, trichloroethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	SML =5 mg/kg (sum of phosphite and phosphate)
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	
74480	000088-99-3	o-Phthalic acid	

▼M4

▼C2

74560	000085-68-7	Phthalic acid, benzyl butyl ester	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML = 30 mg/kg food simulant.
74640	000117-81-7	Phthalic acid, bis (2-ethylhexyl) ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product. SML = 1,5 mg/kg food simulant.
74880	000084-74-2	Phthalic acid, dibutyl ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefines in concentrations up to 0,05 % in the final product. SML = 0,3 mg/kg food simulant.

▼C2

(1)	(2)	(3)	(4)
75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than 60 % C_9.	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ([42]).
75105	068515-49-1 026761-40-0	Phthalic acid, diesters with primary, saturated C_9-C_{11} alcohols more than 90 % C_{10}	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ([42]).

▼C1

76320	000085-44-9	Phthalic anhydride	

▼M3

76415	019455-79-9	Pimelic acid, calcium salt	

▼M5

76463	—	Polyacrylic acid, salts	SML(T) = 6 mg/kg (36) (for acrylic acid)

▼C1

76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6800)	In compliance with the specifications laid down in Annex V

▼M5

76723	167883-16-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4′-diisocyanate	In compliance with the specifications laid down in Annex V
76725	661476-41-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	In compliance with the specifications laid down in Annex V

▼C1

76730	—	Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg

▼C1

(1)	(2)	(3)	(4)
▼M3			
76815	—	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C_{12}-C_{22} fatty acids	In compliance with the specifications laid down in Annex V
76845	031831-53-5	►M4 ►C2 Polyester of 1,4-butanediol with caprolactone ◄ ◄	►M4 ►C2 The restriction for Ref. No 14260 and Ref. No 13720 shall be respected. In compliance with the specifications laid down in Annex V. ◄ ◄
▼M2			
76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol	SML = 30 mg/kg
▼C1			
76960	025322-68-3	Polyethyleneglycol	
▼M3			
77370	070142-34-6	Polyethyleneglycol-30 dipolyhydroxystearate	
▼C1			
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	
▼M5			
77732	—	Polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77733	—	Polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
▼C1			
77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	►M2 SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V ◄
▼M5			
77897	—	Polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C_8-C_{20}) sulphate, salts	SML = 5 mg/kg
▼C1			
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	

▼C1

(1)	(2)	(3)	(4)
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	
▼M3			
79600	009046-01-9	Polyethyleneglycol tridecyl ether phosphate	SML = 5 mg/kg. For materials and articles intended for contact with aqueous foods only. In compliance with the specification laid down in Annex V
▼M4			
▼C2			
79920	009003-11-6 106392-12-5	Poly(ethylene propylene) glycol	
▼M3			
80000	009002-88-4	Polyethylene wax	
▼C1			
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl (C_2-C_4) dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
80800	025322-69-4	Polypropyleneglycol	
▼M3			
81060	009003-07-0	Polypropylene wax	
▼C1			
81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-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
▼M4			
▼C2			
81500	9003-39-8	Polyvinylpyrrolidone	In compliance with the specifications laid down in Annex V.
▼C1			
81515	087189-25-1	Poly(zinc glycerolate)	►M3 SML(T) = 25 mg/kg ([38]) (as Zinc) ◄
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	

▼C1

(1)	(2)	(3)	(4)
81760	—	►M4 ►C2 Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron ◄ ◄	►M4 ►C2 SML(T) = 5 mg/kg ([7]) (expressed as copper); SML = 48 mg/kg (expressed as 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	
82960	001330-80-9	1,2-Propyleneglycol monooleate	
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	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
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	

▼C1

(1)	(2)	(3)	(4)
84560	009006-04-6	Rubber, natural	
84640	000069-72-7	Salicylic acid	
85360	000109-43-3	Sebacic acid, dibutyl ester	
▼M2			
———————			
85601	—	Silicates, natural (with the exception of asbestos)	
▼C1			
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	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).
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	
87520	062568-11-0	Sorbitan monobehenate	
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	

▼C1

(1)	(2)	(3)	(4)
88640	008013-07-8	►M4 ►C2 Soybean oil, epoxidised ◄ ◄	►M4 ►C2 SML = 60 mg/kg. However in the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 91/321/EEC or containing processed cereal-based foods and baby foods for infants and young children as defined by Directive 96/5/EC, the SML is lowered to 30 mg/kg. In compliance with the specifications laid down in Annex V. ◄ ◄
88800	009005-25-8	Starch, edible	
88880	068412-29-3	Starch, hydrolysed	
88960	000124-26-5	Stearamide	
89040	000057-11-4	Stearic acid	

▼M5

89120	000123-95-5	Stearic acid, butyl ester	

▼C1

89200	007617-31-4	Stearic acid, copper salt	►M3 SML(T) = 5 mg/kg ([7]) (expressed as Copper) ◄
89440	—	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/kg ([3])
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	►M3 SML(T) = 5 mg/kg ([7]) (expressed as Copper) ◄
92080	014807-96-6	Talc	
92150	001401-55-4	Tannic acids	According to the JECFA specifications
92160	000087-69-4	Tartaric acid	
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-[5.1.11.2]-heneicosan-21-one, polymer	SML = 5 mg/kg

▼C1

(1)	(2)	(3)	(4)
92930	120218-34-0	Thiodiethanolbis(5-methoxy-carbonyl-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
▼M4			
▼C2			
93760	000077-90-7	Tri-n-butyl acetyl citrate	
▼C1			
94320	000112-27-6	Triethyleneglycol	
94960	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
▼M2			
95000	028931-67-1	Trimethylolpropane trimetha-crylate-methyl methacrylate copolymer	
▼M4			
▼C2			
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	SML = 5 mg/kg food. To be used in single-use gloves only.
▼C1			
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)
▼M4			
▼C2			
95420	745070-61-5	1,3,5-tris (2,2-dimethylpropa-namido)benzene	SML = 0,05 mg/kg food.
▼C1			
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
▼M5			
95858	—	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feed-stocks	SML = 0,05 mg/kg and in compliance with the specifi-cations laid down in Annex V. Not to be used for articles in contact with fatty foods.
▼C1			
95859	—	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifi-cations laid down in Annex V
95883	—	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifi-cations laid down in Annex V

▼C1

(1)	(2)	(3)	(4)
95905	013983-17-0	Wollastonite	
95920	—	Wood flour and fibers, untreated	
95935	011138-66-2	Xanthan gum	
96190	020427-58-1	Zinc hydroxide	►M3 SML(T) = 25 mg/kg ([38]) (as Zinc) ◄
96240	001314-13-2	Zinc oxide	►M3 SML(T) = 25 mg/kg ([38]) (as Zinc) ◄
96320	001314-98-3	Zinc sulphide	►M3 SML(T) = 25 mg/kg ([38]) (as Zinc) ◄

▼C1

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)
▼M3				
	31500	025134-51-4	Acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	SML(T) = 6 mg/kg ([36]) (expressed as acrylic acid) and SML = 0,05 mg/kg (expressed as acrylic acid, 2-ethylhexyl ester)
▼C1				
	31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methyl-benzyl)-4-methylphenyl ester	SML = 6 mg/kg
	31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg ([1])
▼M5				
	34130	—	Alkyl, linear with even number of carbon atoms (C_{12}-C_{20}) dimethylamines	SML = 30 mg/kg
▼C1				
	34230	—	Alkyl(C_8-C_{22})sulphonic acids	SML = 6 mg/kg
▼M2				
	34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butyl-phenyl) phosphate	SML = 5 mg/kg
▼M4				
▼C2				
	35760	001309-64-4	antimony trioxide	SML = 0,04 mg/kg ([39]) (expressed as antimony)
▼C1				
	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)
▼M2				
	38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
▼C1				
	38240	000119-61-9	Benzophenone	SML = 0,6 mg/kg
▼M3				
	38505	351870-33-2	cis-endo-Bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt	SML = 5 mg/kg. Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %
▼C1				
	38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzox-azolyl)thiophene	SML = 0,6 mg/kg
	38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis (isooctyl mercaptoacetate)	SML = 18 mg/kg

▼C1

(1)	(2)	(3)	(4)
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
▼M3			
38940	110675-26-8	2,4-Bis(dodecylthiomethyl)-6-methylphenol	SML(T) = 5 mg/kg ([40])
▼C1			
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	►M3 SML(T) = 5 mg/kg ([40]) ◄
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylene-diamine-1,2-dibromoethane, copolymer	SML = 2,4 mg/kg
▼M2			
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	SML = 30 mg/kg
▼C1			
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
▼M2			
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	SML = 3,0 mg/kg

▼M2

(1)	(2)	(3)	(4)
———————			
▼M4			
▼C2			
47500	153250-52-3	N,N′-Dicyclohexyl-2,6-naphthalene dicarboxamide	SML = 5 mg/kg.
▼C1			
47600	084030-61-5	►M4 ►C2 Di-n-dodecyltin bis(isooctyl mercaptoacetate) ◄ ◄	►M4 ►C2 SML(T) = 0,05 mg/kg food ([41]) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride ◄ ◄
48640	000131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg ([15])
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])
▼M3			
49595	057583-35-4	Dimethyltin bis(ethylhexyl mercaptoacetate)	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
▼C1			
49600	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
49840	002500-88-1	Dioctadecyl disulphide	SML = 3 mg/kg
50160	—	Di-n-octyltin bis(n-alkyl(C_{10}-C_{16}) mercaptoacetate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50240	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50360	—	Di-n-octyltin bis(ethyl maleate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50400	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50480	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50560	—	Di-n-octyltin 1,4-butanediol bis (mercaptoacetate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50640	003648-18-8	Di-n-octyltin dilaurate	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50720	015571-60-5	Di-n-octyltin dimaleate	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50800	—	Di-n-octyltin dimaleate, esterified	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50880	—	Di-n-octyltin dimaleate, polymers (n = 2-4)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
50960	069226-44-4	Di-n-octyltin ethyleneglycol bis (mercaptoacetate)	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄

▼C1

(1)	(2)	(3)	(4)
51040	015535-79-2	Di-n-octyltin mercaptoacetate	►M3 SML(T) = 0,006 mg/kg ([17]) (expressed as Tin) ◄
51120	—	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	►M3 SML(T) = 0,006 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
▼M5			
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl) butyrate]	SML = 6 mg/kg
▼M2			
54880	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg ([22])
55200	001166-52-5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg ([34])
55280	001034-01-1	Gallic acid, octyl ester	SML(T) = 30 mg/kg ([34])
55360	000121-79-9	Gallic acid, propyl ester	SML(T) = 30 mg/kg ([34])
▼C1			
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]benzo-triazole	SML = 1,5 mg/kg
60400	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzo-triazole	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-hexyloxybenzo-phenone	SML(T) = 6 mg/kg ([15])
61360	000131-57-7	2-Hydroxy-4-methoxybenzo-phenone	SML(T) = 6 mg/kg ([15])
61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl) benzotriazole	SML(T) = 30 mg/kg ([19])
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzo-phenone	SML(T) = 6 mg/kg ([15])

▼C1

(1)	(2)	(3)	(4)
63200	051877-53-3	Lactic acid, manganese salt	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
▼M3			
63940	008062-15-5	Lignosulphonic acid	SML = 0,24 mg/kg and to be used only as dispersant for plastics dispersions
▼C1			
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)
▼M3			
66350	085209-93-4	2,2′-Methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	SML = 5 mg/kg and SML(T) = 0,6 ([8]) (expressed as Lithium)
▼C1			
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	►M4 ►C2 Mono-n-dodecyltin tris(isooctyl mercaptoacetate) ◄ ◄	►M4 ►C2 SML(T) = 0,05 mg/kg food ([41]) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride ◄ ◄
▼M3			
67515	057583-34-3	Monomethyltin tris(ethylhexyl mercaptoacetate)	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
▼C1			
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)

▼C1

(1)	(2)	(3)	(4)
67760	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1,2 mg/kg ([18]) (expressed as Tin)
▼M2			
67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
———————			
▼C1			
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
68400	010094-45-8	Octadecylerucamide	SML = 5 mg/kg
68860	004724-48-5	n-Octylphosphonic acid	SML = 0,05 mg/kg
▼M3			
69160	014666-94-5	Oleic acid, cobalt salt	SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt)
▼C1			
69840	016260-09-6	Oleylpalmitamide	SML = 5 mg/kg
▼M2			
71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0,05 mg/kg ([31])
▼M5			
72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)	In compliance with the specifications laid down in Annex V
▼C1			
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)
74400	—	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	SML = 30 mg/kg
▼M3			
———————			
▼M4			
▼C2			
———————			
▼C1			
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

▼C1

(1)	(2)	(3)	(4)
81680	007681-11-0	Potassium iodide	SML(T) = 1 mg/kg ([11]) (expressed as Iodium)
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)
▼M3			
85950	037296-97-2	Silicic acid, magnesium-sodium-fluoride salt	SML = 0,15 mg/kg (expressed as fluoride). Only to be used in layers of multilayers materials not coming into direct contact with food
▼M2			
86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg ([30]) (expressed as $S0_2$)
▼C1			
86800	007681-82-5	Sodium iodide	SML(T) = 1 mg/kg ([11]) (expressed as Iodine)
86880	—	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9 mg/kg
▼M2			
86920	007632-00-0	Sodium nitrite	SML = 0,6 mg/kg
86960	007757-83-7	Sodium sulphite	SML(T) = 10 mg/kg ([30]) (expressed as $S0_2$)
87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg ([30]) (expressed as $S0_2$)
▼C1			
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'-biphenylylene diphosphonite	SML = 18 mg/kg
92800	000096-69-5	4,4'-Thiobis(6-terc-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

▼C1

(1)	(2)	(3)	(4)
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])
▼M4			
▼C2			
93970	—	Tricyclodecanedimethanol bis (hexahydrophthalate)	SML = 0,05 mg/kg.
▼M2			
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methyl-phenyl) propionate]	SML = 9 mg/kg
▼C1			
94560	000122-20-3	Triisopropanolamine	SML = 5 mg/kg
▼M2			
———————			
▼M3			
95265	227099-60-7	1,3,5-Tris(4-benzoylphenyl) benzene	SML = 0,05 mg/kg
▼C1			
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

▼**M2**

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

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

▼M4

▼C2

ANNEX IVa

LIPOPHILIC SUBSTANCES FOR WHICH THE FRF APPLIES

Ref. No	CAS No	Name
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl) ethyl]phenyl ester
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester
▼M5 34130	—	Alkyl, linear with even number of carbon atoms (C12-C20) dimethylamines
▼C2 38240	000119-61-9	Benzophenone
38515	001533-45-5	4,4′-Bis(2-benzoxazolyl)stilbene
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)
38800	032687-78-8	N,N′-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritoldiphosphite
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane
▼M5 39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene
▼C2 39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol
40800	013003-12-8	4,4′-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)
42000	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol
47540	027458-90-8	Di-tert-dodecyl disulphide
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)
48800	000097-23-4	2,2′-Dihydroxy-5,5′-dichlorodiphenylmethane
48880	000131-53-3	2,2′-Dihydroxy-4-methoxybenzophenone
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)-phenol
49840	002500-88-1	Dioctadecyl disulphide

▼C2

Ref. No	CAS No	Name
51680	000102-08-9	N,N′-Diphenylthiourea
52320	052047-59-3	2-(4-Dodecylphenyl)indole
53200	023949-66-8	2-Ethoxy-2′-ethyloxanilide
▼M5		
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]
▼C2		
54300	118337-09-0	2,2′-Ethylidenebis(4,6-di-tert-butyl phenyl) fluorophosphonite
59120	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)
59200	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl–4-hydroxyphenyl)propionate)
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole
60400	003896-11-5	2-(2′-Hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole
60480	003864-99-1	2-(2′-Hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone
66360	085209-91-2	2,2′-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate
66400	000088-24-4	2,2′-Methylene bis(4-ethyl-6-tert-butylphenol)
66480	000119-47-1	2,2′-Methylene bis(4-methyl-6-tert-butylphenol)
66560	004066-02-8	2,2′-Methylene bis(4-methyl-6-cyclohexylphenol)
66580	000077-62-3	2,2′-Methylene bis(4-methyl-6-(1-methyl-cyclohexyl) phenol)
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]
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
68400	010094-45-8	Octadecylerucamide
69840	016260-09-6	Oleylpalmitamide
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)
72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)
72160	000948-65-2	2-Phenylindole
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester
73160	—	Phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester
74400	—	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester
76866	—	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_{12}-C_{18} or n-octanol and/or n-decanol
77440	—	Polyethyleneglycol diricinoleate
78320	009004-97-1	Polyethyleneglycol monoricinoleate

▼C2

Ref. No	CAS No	Name
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]
83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin
83700	000141-22-0	Ricinoleic acid
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester
92320	—	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid
92560	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4′-biphenylylene diphosphonite
92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro [5.1.11.2]-heneicosan-21-one, polymer
92800	000096-69-5	4,4′-Thiobis(6-tert-butyl-3-methylphenol)
92880	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)
93120	000123-28-4	Thiodipropionic acid, didodecyl ester
93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite
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
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
95600	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane

▼C1

ANNEX V

SPECIFICATIONS

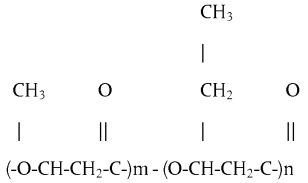
▼M4
▼C2

Part A: General specifications

Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). The migration of the primary aromatic amines appearing in the lists in Annex II and III is excluded from this restriction.

▼C1

Part B: Other specifications

Ref. No	OTHER SPECIFICATIONS
▼M2	
11530	Acrylic acid, 2-hydroxypropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 002918-23-2)
16690	Divinylbenzene It may contain up to 45 % (m/m) of Ethylvinylbenzene
18888	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer
	Definition: The copolymers are produced by the controlled fermentation of Alcaligenes eutrophus 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 Alcaligenes eutrophus 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
	Chemical name: Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number: 080181-31-3
	Structural formula:  where n/(m + n) greater than 0 and less or equal to 0,25
	Average molecular weight: Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay: Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydoxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids
	Description: White to off-white powder after isolation

▼M2

Ref. No	OTHER SPECIFICATIONS	
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	Restriction	QMA for crotonic acid is 0.05 mg/6 dm^2
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— nitrogen	Not more than 2 500 mg/kg of plastic
	— zinc	Not more than 100 mg/kg of plastic
	— copper	Not more than 5 mg/kg of plastic
	— lead	Not more than 2 mg/kg of plastic
	— arsenic	Not more than 1 mg/kg of plastic
	— chromium	Not more than 1 mg/kg of plastic
▼C1		
23547	Polydimethylsiloxane (Mw > 6 800)	
	Minimum viscosity 100 × 10^{-6} m^2/s (= 100 centistokes) at 25 °C	
▼M3		
24903	Syrups, hydrolysed starch, hydrogenated	
	In compliance with the purity criteria for maltitol syrup E 965(ii) (Commission Directive 95/31/EC (OJ L 178, 28.7.1995, p. 1) as last amended by 2004/46/EC (OJ L 114, 21.04.2004, p. 15))	
▼C1		
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)	
▼M4		
▼C2		
42080	Carbon black *Specifications:* — Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. — UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. — Benzo(a)pyrene content: max 0,25 mg/kg carbon black. — Maximum use level of carbon black in the polymer: 2,5 % w/w	
▼M3		
43480	Charcoal, activated	
	To be used only in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC ((OJ L 226,	

▼M3

Ref. No	OTHER SPECIFICATIONS
	22.9.1995, p. 1). Directive as last amended by Directive 2004/47/EC (OJ L 113, 20.4.2004, p. 24)) with exception of ash content which can be up to 10 % (w/w)
▼C1	
43680	Chlorodifluoromethane Content of chlorofluoromethane less than 1 mg/kg of the substance
47210	Dibutylthiostannoic acid polymer Molecular unit = $(C_8H_{18}S_3Sn_2)n$ (n = 1,5-2)
▼M5	
60025	Specifications: — Minimum viscosity (at 100 °C) = 3,8 cSt — Average Mw > 450
▼M3	
64990	Maleic anhydride-styrene, copolymer, sodium salt MW fraction < 1 000 is less than 0,05 % (w/w)
67155	Mixture of 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxazolyl) stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene Mixture obtained from the manufacturing process in the typical ratio of (58-62 %):(23-27 %): (13-17 %)
▼M4 ▼C2	
72081/10	Petroleum hydrocarbon resins (hydrogenated) *Specifications:* Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoid arylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. *Properties:* Viscosity: > 3 Pa.s at 120 °C Softening point: > 95 °C as determined by ASTM Method E 28-67 Bromine number: < 40 (ASTM D1159) The colour of a 50 % solution in toluene < 11 on the Gardner scale Residual aromatic monomer ≤ 50 ppm
▼C1	
76721	Polydimethylsiloxane (Mw > 6 800) Minimum viscosity 100×10^{-6} m^2/s (= 100 centistokes) at 25 °C
▼M5	
76723	Specifications: The fraction with molecular weight below 1 000 should not exceed 1,5 % w/w

▼M5

Ref. No	OTHER SPECIFICATIONS
76725	Specifications: The fraction with molecular weight below 1 000 should not exceed 1 % w/w
▼M4 ▼C2 76845	Polyester of 1,4-butanediol with caprolactone MW fraction < 1 000 is less than 0,5 % (w/w)
▼M3 76815	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C12-C22 fatty acids MW fraction < 1 000 is less than 5 % (w/w)
▼M2 77895	Polyethyleneglycol (E0 = 2-6) monoalkyl (C_{16}-C_{18}) ether The composition of this mixture is as follows: — polyethyleneglycol (E0 = 2-6)monoalkyl (C_{16}-C_{18}) ether (approximately 28 %) — fatty alcohols (C_{16}-C_{18}) (approximately 48 %) — ethyleneglycol monoalkyl (C_{16}-C_{18}) ether (approximately 24 %)
▼M3 79600	Polyethyleneglycol tridecyl ether phosphate Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono-and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether
▼M4 ▼C2 81500	Polyvinylpyrrolidone The substance shall meet the purity criteria established in Commission Directive 96/77/EC (**)
▼C1 83595	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 Composition: — 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-butyl-phenyl)phosphonite (CAS.No 112949-97-0) (< 5 % w/w (*)). Other specifications: — Phosphor content of min. 5,4 % to max. 5,9 %

▼C1

Ref. No	OTHER SPECIFICATIONS
	— Acid value of max. 10 mg KOH per gram — Melt range of 85-110 °C
▼M4 ▼C2	
88640	Soybean oil, epoxidized Oxirane < 8 %, iodine number < 6
▼M5	
95858	Specifications: — Average molecular weight not less than 350 — Viscosity at 100 °C min 2,5 cSt — Content of hydrocarbons with carbon number less than 25, not more than 40 % w/w
▼C1	
95859	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks The product should have the following specifications: — Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w) — Viscosity not less than 11×10^{-6} m^2/s (= 11 centistokes) at 100 °C — Average molecular weight not less than 500.
95883	White mineral oils, paraffinic derived from petroleum based hydrocarbon feedstocks The product should have the following specifications: — Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w) — Viscosity not less than $8,5 \times 10^{-6}$ m^2/s (= 8,5 centistokes) at 100 °C — Average molecular weight not less than 480

(*) Quantity of substance used /quantity of formulation
►M4 ►C2 (**) OJ L 339, 30.12.1996, p. 1. ◄ ◄

▼M2

ANNEX VI

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

([1]) Warning: there is a risk that the SML could be exceeded in fatty food simulants.

([2]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 10060 and 23920.

([3]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 15760, 16990, 47680, 53650 and 89440.

([4]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 19540, 19960 and 64800.

([5]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 14200, 14230 and 41840.

([6]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 66560 and 66580.

([7]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.

▼M4

▼C2

([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: 24886, 38000, 42400, 62020, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.

▼M2

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

([10]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.

([11]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels (expressed as Iodine) of the following substances mentioned as reference Nos: 45200, 64320, 81680 and 86800.

([12]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 36720, 36800, 36840 and 92000.

([13]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 39090 and 39120.

▼M3

([14]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 44960, 68078, 69160, 82020 and 89170.

▼M2

([15]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

▼M3

([16]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 49595, 49600, 67520, 67515 and 83599.

▼M2

([17]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.

([18]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 67600, 67680 and 67760.

([19]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 60400, 60480 and 61440.

([20]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 66400 and 66480.

([21]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 93120 and 93280.

([22]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 17260, 18670, 54880 and 59280.

([23]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13620, 36840, 40320 and 87040.

([24]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13720 and 40580.

([25]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 16650 and 51570.

([26]) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

([27]) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 10599/90A, 10599/91, 10599/92A and 10599/93.

([28]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13480 and 39680.

([29]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 22775 and 69920.

([30]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 86480, 86960 and 87120

([31]) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.

([32]) Compliance testing when there is a fat contact should be performed using isoctane as substitute of simulant D (unstable).

([33]) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14800 and 45600.

([34]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 55200, 55280 and 55360.

▼M3

([35]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 25540 and 25550.

▼M5

([36]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 10690, 10750, 10780, 10810, 10840, 11470, 11590, 11680, 11710, 11830, 11890, 11980, 31500 and 76463.

▼M3

([37]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 20020, 20080, 20110, 20140, 20170, 20890, 21010, 21100, 21130, 21190, 21280, 21340 and 21460.

([38]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 81515, 96190, 96240 and 96320 as well as of salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. The same restriction for Zn applies to the names containing '… acid(s), salts' which appear in the lists, if the corresponding free acid(s) is (are) not mentioned.

([39]) Migration limit might be exceeded at very high temperature.

([40]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 38940 and 40020.

▼M4

▼C2

([41]) 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: 47600, 67360.

([42]) 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: 75100 and 75105.

▼M5

([43]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 19150 and 19180.

▼M4
▼C2

ANNEX VIa

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 9 shall contain the following information:

(1) the identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials and articles;

(2) the identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles;

(3) the date of the declaration;

(4) confirmation that the plastic materials or articles meet relevant requirements laid down in this Directive and Regulation (EC) No 1935/2004;

(5) adequate information relative to the substances used for which restrictions and/or specifications are in place under this Directive to allow the downstream business operators to ensure compliance with those restrictions;

(6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food;

(7) specifications on the use of the material or article, such as:

  (i) type or types of food with which it is intended to be put in contact;

  (ii) time and temperature of treatment and storage in contact with the food;

  (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;

(8) when a plastic functional barrier is used in a plastic multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 7a(2), (3) and 4 of this Directive.

The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

▼C1

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 20041 March 2003 for materials and articles which contain Divinyl-benzene

▼C1

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