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)


Amended by:

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| No   | page | date    |

Corrected by:

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.


(5) Since the rules established in this Directive are not suitable for ion-exchange resins, these materials and articles will be covered by a subsequent specific Directive.

(6) Silicones should be regarded as elastomeric materials rather than plastic materials and therefore should be excluded from the definition of plastic.

(7) The establishment of a list of approved substances accompanied by a limit on overall migration and, where necessary, by other specific restrictions will be sufficient to achieve the objective laid down in Article 2 of Directive 89/109/EEC.

(8) Besides the monomers and other starting substances fully evaluated and authorised at Community level, there are also monomers and starting substances evaluated and authorised in at least one Member State which may continue to be used pending their evaluation by the Scientific Committee on Food and the decision on their inclusion in the Community list; this Directive will accordingly be extended in due course to the substances and sectors provisionally excluded.

(9) The current list of additives is an incomplete list inasmuch as it does not contain all the substances which are currently accepted in one or more Member States; accordingly, these substances continue to be regulated by national laws pending a decision on inclusion in the Community list.

(10) This Directive establishes specifications for only a few substances. The other substances, which may require specifications, therefore remain regulated in this respect by national laws pending a decision at Community level.

(11) For certain additives the restrictions established in this Directive cannot yet be applied in all situations pending the collection and evaluation of all the data needed for a better estimation of the exposure of the consumer in some specific situations; therefore, these additives appear in a list other than that of the additives fully regulated at Community level.

(12) Directive 82/711/EEC lays down the basic rules necessary for testing migration of the constituents of plastic materials and articles and Council Directive 85/572/EEC (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. 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.

(2) OJ L 44, 15.2.1978, p. 15.
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.

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

This Directive should be without prejudice to the deadlines set out in Annex VII, Part B within which the Member States are to comply with Directive 90/128/EEC, and the acts amending it,

HAS ADOPTED THIS DIRECTIVE:

**Article 1**

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.

2. This Directive shall apply to plastic materials and articles and parts thereof:

   (a) consisting exclusively of plastics; or

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

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

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

   However, the following shall not be regarded as ‘plastics’:

   (a) varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC (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.

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

**Article 2**

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre

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of surface area of material or article (mg/dm²) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);

(b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

(c) caps, gaskets, stoppers or similar devices for sealing.

Article 3

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).

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

— either by adding substances listed in Annex II, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or

— by including ‘new substances’, i.e. substances which are listed neither in Section A nor in Section B of Annex II, according to Article 3 of Directive 89/109/EEC.

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

5. The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

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

— epoxy resins,

— adhesives and adhesion promoters,

— printing inks.

Article 4

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

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

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

2. For the additives listed in Annex III, section B, the verification of compliance with the specific migration limits in 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 1 July 2006.
3. The lists in Annex III, sections A and B do not yet include the following additives:

(a) additives used only in the manufacture of:

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

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

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

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

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

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

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

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

Article 4b

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

Article 5

Only the products obtained by means of bacterial fermentation listed in Annex IV may be used in contact with foodstuffs.
Article 5a

5. 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.

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

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

Article 6

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

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

Article 7

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

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 1 l;

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

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

Article 8

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

2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if the value of

(1) OJ L 40, 11.2.1989, p. 27.
(2) OJ L 184, 15.7.1988, p. 61.
overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.

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

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

Article 9

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

(a) be in accordance with Article 6(5) of Directive 89/109/EEC;

(b) provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC (1), 95/45/EC (2) and 2002/82/EC (3) to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

Article 10


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.

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.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article. The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.

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

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

4. In accordance with the provisions set out in Article 8 of the present Directive, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.

5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

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

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

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

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

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M₁). 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 (M₂ and M₃, respectively).

The material or article shall be deemed to be in compliance provided that either M₁ or M₃ - M₂ 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/dm² in migration tests using rectified olive oil or substitutes,

— 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

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

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

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.

3. The list also does not include the following substances although they may be present:
   (a) substances which could be present in the finished product as:
      — impurities in the substances used,
      — reaction intermediates,
      — decomposition products;
   (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;
   (c) mixtures of the authorised substances.

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

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

5. The list contains the following information:
   — column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
   — column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
   — column 3 (Name): the chemical name,
   — column 4 (Restrictions and/or specifications): These may include:
     — specific migration limit (SML),
     — maximum permitted quantity of the substance in the finished material or article (QM),
     — maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

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

8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

- **DL** = Detection limit of the method of analysis;
- **FP** = Finished material or article;
- **NCO** = Isocyanate moiety;
- **ND** = not detectable. For the purpose of this Directive ‘not detectable’ means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;
- **QM** = Maximum permitted quantity of the ‘residual’ substance in the material or article. 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;
- **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 material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- **QMA(T)** = Maximum permitted quantity of the ‘residual’ substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- **SML** = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Directive the specific migration of the substance should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- **SML(T)** = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.
### Section A

List of authorised monomers and other starting substances

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>CAS No</th>
<th>Name</th>
<th>Restrictions and/or specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>10030</td>
<td>000514-10-3</td>
<td>Abietic acid</td>
<td>SML(T) = 6 mg/kg (2)</td>
</tr>
<tr>
<td>10060</td>
<td>000075-07-0</td>
<td>Acetaldehyde</td>
<td></td>
</tr>
<tr>
<td>10090</td>
<td>000064-19-7</td>
<td>Acetic acid</td>
<td></td>
</tr>
<tr>
<td>10120</td>
<td>000108-05-4</td>
<td>Acetic acid, vinyl ester</td>
<td>SML = 12 mg/kg</td>
</tr>
<tr>
<td>10150</td>
<td>000108-24-7</td>
<td>Acetic anhydride</td>
<td></td>
</tr>
<tr>
<td>10210</td>
<td>000074-86-2</td>
<td>Acetylene</td>
<td></td>
</tr>
<tr>
<td>10599/90A</td>
<td>061788-89-4</td>
<td>Acids, fatty, unsaturated (C₁₈), dimers, distilled</td>
<td>QMA(T) = 0.05 mg/6 dm² (27)</td>
</tr>
<tr>
<td>10599/91</td>
<td>061788-89-4</td>
<td>Acids, fatty, unsaturated (C₁₈), dimers, non distilled</td>
<td>QMA(T) = 0.05 mg/6 dm² (27)</td>
</tr>
<tr>
<td>10599/92A</td>
<td>068783-41-5</td>
<td>Acids, fatty, unsaturated (C₁₈), dimers, hydrogenated, distilled</td>
<td>QMA(T) = 0.05 mg/6 dm² (27)</td>
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<tr>
<td>10599/93</td>
<td>068783-41-5</td>
<td>Acids, fatty, unsaturated (C₁₈), dimers, hydrogenated, non distilled</td>
<td>QMA(T) = 0.05 mg/6 dm² (27)</td>
</tr>
<tr>
<td>10630</td>
<td>000079-06-1</td>
<td>Acrylamide</td>
<td>SML = ND (DL = 0.01 mg/kg)</td>
</tr>
<tr>
<td>10660</td>
<td>015214-89-8</td>
<td>2-Acrylamido-2-methylpropanesulphonic acid</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>10690</td>
<td>000079-10-7</td>
<td>Acrylic acid</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
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<tr>
<td>10750</td>
<td>002495-35-4</td>
<td>Acrylic acid, benzyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
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<td>10780</td>
<td>000141-32-2</td>
<td>Acrylic acid, n-butyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>10810</td>
<td>002998-08-5</td>
<td>Acrylic acid, sec-butyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>10840</td>
<td>001663-39-4</td>
<td>Acrylic acid, tert-butyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>11005</td>
<td>012542-30-2</td>
<td>Acrylic acid, dicyclopentenyl ester</td>
<td>QMA = 0.05 mg/6 dm²</td>
</tr>
<tr>
<td>11245</td>
<td>002156-97-0</td>
<td>Acrylic acid, dodecyl ester</td>
<td>SML = 0.05 mg/kg (1)</td>
</tr>
<tr>
<td>11470</td>
<td>000140-88-5</td>
<td>Acrylic acid, ethyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>11500</td>
<td>000103-11-7</td>
<td>Acrylic acid, 2-ethylhexyl ester</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>11510</td>
<td>000818-61-1</td>
<td>Acrylic acid, hydroxyethyl ester</td>
<td>See ‘Acrylic acid, monoester with ethyleneglycol’</td>
</tr>
<tr>
<td>11530 ▶M2</td>
<td>009999-61-1</td>
<td>Acrylic acid, 2-hydroxypropyl ester</td>
<td>▶M2 QMA = 0.05 mg/6 dm² 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</td>
</tr>
<tr>
<td>11590</td>
<td>000106-63-8</td>
<td>Acrylic acid, isobutyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>11680</td>
<td>000689-12-3</td>
<td>Acrylic acid, isopropyl ester</td>
<td>▶M3 SML(T) = 6 mg/kg (36)</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>-------------------------------------------------</td>
</tr>
<tr>
<td>11710</td>
<td>000096-33-3</td>
<td>Acrylic acid, methyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (°) ◄</td>
</tr>
<tr>
<td>11830</td>
<td>000818-61-1</td>
<td>Acrylic acid, monoester with ethyleneglycol</td>
<td>►M3 SML(T) = 6 mg/kg (°) ◄</td>
</tr>
<tr>
<td>11890</td>
<td>002499-59-4</td>
<td>Acrylic acid, n-octyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (°) ◄</td>
</tr>
<tr>
<td>11980</td>
<td>000925-60-0</td>
<td>Acrylic acid, propyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (°) ◄</td>
</tr>
<tr>
<td>12100</td>
<td>000107-13-1</td>
<td>Acrylonitrile</td>
<td>SML = ND (DL = 0,020 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>12130</td>
<td>000124-04-9</td>
<td>Adipic acid</td>
<td></td>
</tr>
<tr>
<td>12265</td>
<td>004074-90-2</td>
<td>Adipic acid, divinyl ester</td>
<td>QM = 5 mg/kg in FP. Or use only as comonomer</td>
</tr>
<tr>
<td>12280</td>
<td>002035-75-8</td>
<td>Adipic anhydride</td>
<td></td>
</tr>
<tr>
<td>12310</td>
<td></td>
<td>Albumin</td>
<td></td>
</tr>
<tr>
<td>12340</td>
<td></td>
<td>Albumin, coagulated by formaldehyde</td>
<td></td>
</tr>
<tr>
<td>12375</td>
<td></td>
<td>Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)</td>
<td></td>
</tr>
<tr>
<td>12670</td>
<td>002855-13-2</td>
<td>1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>12765</td>
<td>000693-57-2</td>
<td>12-Aminododecanoic acid</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>12763</td>
<td>000141-43-5</td>
<td>2-Aminoethanol</td>
<td>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</td>
</tr>
<tr>
<td>12765</td>
<td>084434-12-8</td>
<td>N-(2-Aminoethyl)-beta-alanine, sodium salt</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>12786</td>
<td>000919-30-2</td>
<td>3-Aminopropyltriethoxysilane</td>
<td>Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler. To be used only for the reactive surface treatment of inorganic fillers</td>
</tr>
<tr>
<td>12788</td>
<td>002432-99-7</td>
<td>11-Aminoundecanoic acid</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>12789</td>
<td>007664-41-7</td>
<td>Ammonia</td>
<td></td>
</tr>
<tr>
<td>12820</td>
<td>000123-99-9</td>
<td>Azelaic acid</td>
<td></td>
</tr>
<tr>
<td>12970</td>
<td>004196-95-6</td>
<td>Azelaic anhydride</td>
<td></td>
</tr>
<tr>
<td>13000</td>
<td>001477-55-0</td>
<td>1,3-Benzenedimethamine</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>13060</td>
<td>004422-95-1</td>
<td>1,3,5-Benzentricarboxylic acid trichloride</td>
<td>QMA = 0,05 mg/6 dm³ (measured as 1,3,5-Benzentricarboxylic acid)</td>
</tr>
<tr>
<td>13075</td>
<td>000091-76-9</td>
<td>Benzoguanamine</td>
<td>See ‘2,4-Diamino-6-phenyl-1,3,5-triazine’</td>
</tr>
<tr>
<td>13090</td>
<td>000065-85-0</td>
<td>Benzoic acid</td>
<td></td>
</tr>
<tr>
<td>13150</td>
<td>000100-51-6</td>
<td>Benzyl alcohol</td>
<td></td>
</tr>
<tr>
<td>13180</td>
<td>000498-66-8</td>
<td>Bicyclo[2.2.1]hept-2-ene (=Norbornene)</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>13210</td>
<td>001761-71-3</td>
<td>Bis(4-aminocyclohexyl)methane</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
</tr>
<tr>
<td>---------</td>
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<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td>▼M3</td>
<td>13317</td>
<td>132459-54-2 N,N'-Bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide</td>
<td>SML = 0.05 mg/kg. Purity &gt; 98.1 % (w/w). To be used only as co-monomer (max 4 %) for polyesters (PET, PBT)</td>
</tr>
<tr>
<td>▼M2</td>
<td>13323</td>
<td>000102-40-9 1,3-Bis(2-hydroxyethoxy)benzene</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>▼C1</td>
<td>13326</td>
<td>000111-46-6 Bis(2-hydroxyethyl)ether</td>
<td>See ‘Diethylenglycol’</td>
</tr>
<tr>
<td></td>
<td>13380</td>
<td>000077-99-6 2,2-Bis(hydroxymethyl)-1-butanol</td>
<td>See ‘1,1,1-Trimethylolpropane’</td>
</tr>
<tr>
<td></td>
<td>13390</td>
<td>000105-08-8 1,4-Bis(hydroxymethyl)cyclohexane</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13395</td>
<td>004767-03-7 2,2-Bis(hydroxymethyl)propionic acid</td>
<td>QMA = 0.05 mg/6 dm²</td>
</tr>
<tr>
<td></td>
<td>13480</td>
<td>000080-05-7 2,2-Bis(4-hydroxyphenyl)propylene</td>
<td>▲M2 SML(T) = 0.6 mg/kg (25)</td>
</tr>
<tr>
<td></td>
<td>13510</td>
<td>001675-54-3 2,2-Bis(4-hydroxyphenyl)propene bis(2,3-epoxypropyl) ether (=BADGE)</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td>13530</td>
<td>038103-06-9 2,2-Bis(4-hydroxyphenyl)propene bis(phthalic anhydride)</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td></td>
<td>13550</td>
<td>000110-98-5 Bis(hydroxypropyl) ether</td>
<td>See ‘Dipropyleneenglycol’</td>
</tr>
<tr>
<td></td>
<td>13560</td>
<td>0005124-30-1 Bis(4-isocyanatocyclohexyl)methane</td>
<td>See ‘Dicyclohexylmethane-4,4’-diisocyanate</td>
</tr>
<tr>
<td></td>
<td>13600</td>
<td>047465-97-4 3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone</td>
<td>SML = 1.8 mg/kg</td>
</tr>
<tr>
<td></td>
<td>13607</td>
<td>000080-05-7 Bisphenol A</td>
<td>See ‘2,2-Bis(4-hydroxyphenyl)propane’</td>
</tr>
<tr>
<td></td>
<td>13610</td>
<td>001675-54-3 Bisphenol A bis(2,3-epoxypropyl) ether</td>
<td>See ‘2,2-Bis(4-hydroxyphenyl)propene bis(2,3-epoxypropyl) ether’</td>
</tr>
<tr>
<td></td>
<td>13614</td>
<td>038103-06-9 Bisphenol A bis(phthalic anhydride)</td>
<td>See ‘2,2-Bis(4-hydroxyphenyl)propene bis(phthalic anhydride)’</td>
</tr>
<tr>
<td></td>
<td>13617</td>
<td>000080-09-1 Bisphenol S</td>
<td>See ‘4,4’‘-Dihydroxydiphenyl sulphone’</td>
</tr>
<tr>
<td></td>
<td>13630</td>
<td>000106-99-0 Butadiene</td>
<td>QM = 1 mg/kg in FP or SML = not detectable (DL = 0.020 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td></td>
<td>13690</td>
<td>000107-88-0 1,3-Butanediol</td>
<td>▲M3 SML(T) = 5 mg/kg (25)</td>
</tr>
<tr>
<td></td>
<td>13720</td>
<td>000110-63-4 1,4-Butanediol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13780</td>
<td>002425-79-8 1,4-Butanediol bis(2,3-epoxypropyl) ether</td>
<td>QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)</td>
</tr>
<tr>
<td></td>
<td>13810</td>
<td>000505-65-7 1,4-Butanediol formal</td>
<td>QMA = 0.05 mg/6 dm²</td>
</tr>
<tr>
<td></td>
<td>13840</td>
<td>000071-36-3 1-Butanol</td>
<td></td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<tr>
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</tr>
<tr>
<td>13870</td>
<td>000106-98-9</td>
<td>1-Butene</td>
<td></td>
</tr>
<tr>
<td>13900</td>
<td>000107-01-7</td>
<td>2-Butene</td>
<td></td>
</tr>
<tr>
<td>13932</td>
<td>000598-32-3</td>
<td>3-Buten-2-ol</td>
<td>QMA = ND (DL = 0,02 mg/6 dm²) To be used only as a comonomer for the preparation of polymeric additive</td>
</tr>
<tr>
<td>14020</td>
<td>000098-54-4</td>
<td>4-tert-Butylphenol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>14110</td>
<td>000123-72-8</td>
<td>Butyraldehyde</td>
<td></td>
</tr>
<tr>
<td>14140</td>
<td>000107-92-6</td>
<td>Butyric acid</td>
<td></td>
</tr>
<tr>
<td>14170</td>
<td>000106-31-0</td>
<td>Butyric anhydride</td>
<td></td>
</tr>
<tr>
<td>14200</td>
<td>000105-60-2</td>
<td>Caprolactam</td>
<td>SML(T) = 15 mg/kg (1)</td>
</tr>
<tr>
<td>14230</td>
<td>002123-24-2</td>
<td>Caprolactam, sodium salt</td>
<td>SML(T) = 15 mg/kg (1) (expressed as Caprolactam)</td>
</tr>
<tr>
<td>14260</td>
<td>000502-44-3</td>
<td>Caprolactone</td>
<td>SML = 0,05 mg/kg (expressed as the sum of caprolactone and 6-hydroxy-hexanoic acid)</td>
</tr>
<tr>
<td>14320</td>
<td>000124-07-2</td>
<td>Caprylic acid</td>
<td></td>
</tr>
<tr>
<td>14350</td>
<td>000630-08-0</td>
<td>Carbon monoxide</td>
<td></td>
</tr>
<tr>
<td>14380</td>
<td>000075-44-5</td>
<td>Carboxyl chloride</td>
<td>QM = 1 mg/kg in FP</td>
</tr>
<tr>
<td>14411</td>
<td>008001-79-4</td>
<td>Castor oil</td>
<td></td>
</tr>
<tr>
<td>14500</td>
<td>009004-34-6</td>
<td>Cellulose</td>
<td></td>
</tr>
<tr>
<td>14530</td>
<td>007782-50-5</td>
<td>Chlorine</td>
<td></td>
</tr>
<tr>
<td>14570</td>
<td>000106-89-8</td>
<td>1-Chloro-2,3-epoxypropane</td>
<td>See ‘Epichlorohydrin’</td>
</tr>
<tr>
<td>14650</td>
<td>000079-38-9</td>
<td>Chlorotrifluoroethylene</td>
<td>QMA = 0,5 mg/6 dm²</td>
</tr>
<tr>
<td>14680</td>
<td>000077-92-9</td>
<td>Citric acid</td>
<td></td>
</tr>
<tr>
<td>14710</td>
<td>00108-39-4</td>
<td>m-Cresol</td>
<td></td>
</tr>
<tr>
<td>14740</td>
<td>000095-48-7</td>
<td>o-Cresol</td>
<td></td>
</tr>
<tr>
<td>14770</td>
<td>000106-44-5</td>
<td>p-Cresol</td>
<td></td>
</tr>
<tr>
<td>14800</td>
<td>003724-65-0</td>
<td>Crotonic acid</td>
<td>QMA(T) = 0,05 mg/6 dm² (23)</td>
</tr>
<tr>
<td>14841</td>
<td>000599-64-4</td>
<td>4-Cumylphenol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>14880</td>
<td>000105-08-8</td>
<td>1,4-Cyclohexaneditol</td>
<td>See ‘1,4-Bis(hydroxymethyl)cyclohexane’</td>
</tr>
<tr>
<td>14950</td>
<td>003173-53-3</td>
<td>Cyclohexyl isocyanate</td>
<td>◄M2 QM(T) = 1 mg/kg in FP (expressed as NCO) (20) ◄</td>
</tr>
<tr>
<td>15030</td>
<td>000931-88-4</td>
<td>Cyclooctene</td>
<td>SML = 0,05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Directive 85/572/EEC</td>
</tr>
<tr>
<td>15070</td>
<td>001647-16-1</td>
<td>1,9-Decadiene</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>15095</td>
<td>000334-48-5</td>
<td>Decanoic acid</td>
<td></td>
</tr>
<tr>
<td>15100</td>
<td>000112-30-1</td>
<td>1-Decanol</td>
<td></td>
</tr>
<tr>
<td>15130</td>
<td>000872-05-9</td>
<td>1-Decene</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>15250</td>
<td>000110-60-1</td>
<td>1,4-Diaminobutane</td>
<td></td>
</tr>
<tr>
<td>15272</td>
<td>000107-15-3</td>
<td>1,2-Diaminoethane</td>
<td>See ‘Ethylenediamine’</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<tr>
<td>15274</td>
<td>000124-09-4</td>
<td>1,6-Diaminohexane</td>
<td>See ‘Hexamethylenediamine’</td>
</tr>
<tr>
<td>15310</td>
<td>000091-76-9</td>
<td>2,4-Diamino-6-phenyl-1,3,5-triazine</td>
<td>QMA = 5 mg/6 dm²</td>
</tr>
<tr>
<td>▼C1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15565</td>
<td>000106-46-7</td>
<td>1,4-Dichlorobenzene</td>
<td>SML = 12 mg/kg</td>
</tr>
<tr>
<td>15610</td>
<td>000080-07-9</td>
<td>4,4'-Dichlorodiphenyl sulphone</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>15700</td>
<td>005124-30-1</td>
<td>Dicyclohexylmethane-4,4'-diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (26)</td>
</tr>
<tr>
<td>15760</td>
<td>00111-46-6</td>
<td>Diethyleneglycol</td>
<td>SML(T) = 30 mg/kg (\textsuperscript{(1)})</td>
</tr>
<tr>
<td>15790</td>
<td>00111-40-0</td>
<td>Diethylenetriamine</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>15820</td>
<td>000345-92-6</td>
<td>4,4'-Difluorobenzophenone</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>15880</td>
<td>000120-80-9</td>
<td>1,2-Dihydroxybenzene</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>15910</td>
<td>000108-46-3</td>
<td>1,3-Dihydroxybenzene</td>
<td>SML = 2,4 mg/kg</td>
</tr>
<tr>
<td>15940</td>
<td>000123-31-9</td>
<td>1,4-Dihydroxybenzene</td>
<td>SML = 0,6 mg/kg</td>
</tr>
<tr>
<td>15970</td>
<td>000611-99-4</td>
<td>4,4'-Dihydroxybenzophenone</td>
<td>SML(T) = 6 mg/kg (\textsuperscript{(1)})</td>
</tr>
<tr>
<td>16000</td>
<td>000092-88-6</td>
<td>4,4'-Dihydroxybiphenyl</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>16090</td>
<td>000080-09-1</td>
<td>4,4'-Dihydroxydiphenyl sulphone</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>16150</td>
<td>000108-01-0</td>
<td>Dimethylaminooethanol</td>
<td>SML = 18 mg/kg</td>
</tr>
<tr>
<td>▼M2</td>
<td></td>
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</tr>
<tr>
<td>16190</td>
<td>001321-74-0</td>
<td>Divinylbenzene</td>
<td>QMA = 0,01 mg/6 dm\textsuperscript{2} or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylnbenzene and in compliance with the specifications laid down in Annex V</td>
</tr>
<tr>
<td>▼C1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16240</td>
<td>000091-97-4</td>
<td>3,3'-Dimethyl-4,4'-diaminodicyclohexyl-methane</td>
<td>SML = 0,05 mg/kg (\textsuperscript{(2)}) To be used only in polyamides.</td>
</tr>
<tr>
<td>16360</td>
<td>000576-26-1</td>
<td>2,6-Dimethylphenol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>16390</td>
<td>000126-30-7</td>
<td>2,2-Dimethyl-1,3-propanediol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>16450</td>
<td>000646-06-0</td>
<td>1,3-Dioxolane</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>16480</td>
<td>000126-58-9</td>
<td>Dipentaerythritol</td>
<td></td>
</tr>
<tr>
<td>▼M2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16540</td>
<td>000102-09-0</td>
<td>Diphenyl carbonate</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>▼C1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16570</td>
<td>004128-73-8</td>
<td>Diphenylether-4,4'-diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (\textsuperscript{(2)})</td>
</tr>
<tr>
<td>16600</td>
<td>005873-54-1</td>
<td>Diphenylmethane-2,4'-diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (\textsuperscript{(2)})</td>
</tr>
<tr>
<td>16630</td>
<td>000101-68-8</td>
<td>Diphenylmethane-4,4'-diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (\textsuperscript{(2)})</td>
</tr>
<tr>
<td>16650</td>
<td>000127-63-9</td>
<td>Diphenyl sulphone</td>
<td>SML(T) = 3 mg/kg (\textsuperscript{(2)})</td>
</tr>
<tr>
<td>16660</td>
<td>000110-98-5</td>
<td>Dipropyleneeglycol</td>
<td></td>
</tr>
<tr>
<td>16690</td>
<td>001321-74-0</td>
<td>Divinylbenzene</td>
<td></td>
</tr>
<tr>
<td>16694</td>
<td>013811-50-2</td>
<td>N,N'-Divinyl-2-imidazolidinone</td>
<td>QM = 5 mg/kg in FP</td>
</tr>
<tr>
<td>16697</td>
<td>000693-23-2</td>
<td>n-Dodecanedioic acid</td>
<td>QM = 1 mg/kg in FP</td>
</tr>
<tr>
<td>16704</td>
<td>000112-41-4</td>
<td>1-Dodecene</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>16750</td>
<td>000106-89-8</td>
<td>Epichlorohydrin</td>
<td>QM = 5 mg/kg in FP</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>(1)</td>
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<tr>
<td>16780</td>
<td>000064-17-5</td>
<td>Ethanol</td>
<td></td>
</tr>
<tr>
<td>16950</td>
<td>000074-85-1</td>
<td>Ethylene</td>
<td></td>
</tr>
<tr>
<td>16955</td>
<td>000096-49-1</td>
<td>Ethylene carbonate</td>
<td>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</td>
</tr>
<tr>
<td>16960</td>
<td>000107-15-3</td>
<td>Ethylenediamine</td>
<td>SML = 12 mg/kg</td>
</tr>
<tr>
<td>16990</td>
<td>000107-21-1</td>
<td>Ethyleneglycol</td>
<td>SML(T) = 30 mg/kg (1)</td>
</tr>
<tr>
<td>17005</td>
<td>000151-56-4</td>
<td>Ethyleneneimine</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
</tr>
<tr>
<td>17020</td>
<td>000075-21-8</td>
<td>Ethylene oxide</td>
<td>QM = 1 mg/kg in FP</td>
</tr>
<tr>
<td>17050</td>
<td>000104-76-7</td>
<td>2-Ethyl-1-hexanol</td>
<td>SML = 30 mg/kg</td>
</tr>
<tr>
<td>17110</td>
<td>016219-75-3</td>
<td>5-Ethylidenebicyclo[2,2,1]hept-2-ene</td>
<td>QMA = 0,05 mg/6 dm². The ratio surface/quantity of food shall be lower than 2 dm²/kg</td>
</tr>
<tr>
<td>17160</td>
<td>000097-53-0</td>
<td>Eugenol</td>
<td>SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>17170</td>
<td>061788-47-4</td>
<td>Fatty acids, coco</td>
<td></td>
</tr>
<tr>
<td>17200</td>
<td>068308-53-2</td>
<td>Fatty acids, soya</td>
<td></td>
</tr>
<tr>
<td>17230</td>
<td>061790-12-3</td>
<td>Fatty acids, tall oil</td>
<td></td>
</tr>
<tr>
<td>17260</td>
<td>000050-00-0</td>
<td>Formaldehyde</td>
<td>SML(T) = 15 mg/kg (2)</td>
</tr>
<tr>
<td>17290</td>
<td>000110-17-8</td>
<td>Fumaric acid</td>
<td></td>
</tr>
<tr>
<td>17530</td>
<td>000050-99-7</td>
<td>Glucose</td>
<td></td>
</tr>
<tr>
<td>18010</td>
<td>000110-94-1</td>
<td>Glutaric acid</td>
<td></td>
</tr>
<tr>
<td>18070</td>
<td>000108-55-4</td>
<td>Glutaric anhydride</td>
<td></td>
</tr>
<tr>
<td>18100</td>
<td>000056-81-5</td>
<td>Glycerol</td>
<td></td>
</tr>
<tr>
<td>18220</td>
<td>068564-88-5</td>
<td>N-Heptylaminoundecanoic acid</td>
<td>SML = 0,05 mg/kg (1)</td>
</tr>
<tr>
<td>18250</td>
<td>000115-28-6</td>
<td>Hexachloroendomethylenetetrahydroththalic acid</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
</tr>
<tr>
<td>18280</td>
<td>000115-27-5</td>
<td>Hexachloroendomethylenetetrahydroththalic anhydride</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
</tr>
<tr>
<td>18310</td>
<td>036653-82-4</td>
<td>1-Hexadecanol</td>
<td></td>
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<tr>
<td>18430</td>
<td>000116-15-4</td>
<td>Hexafluoropropylene</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
</tr>
<tr>
<td>18460</td>
<td>000124-09-4</td>
<td>Hexamethylenediamine</td>
<td>SML = 2,4 mg/kg</td>
</tr>
<tr>
<td>18640</td>
<td>000822-06-0</td>
<td>Hexamethylene diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (2)</td>
</tr>
<tr>
<td>18670</td>
<td>000100-97-0</td>
<td>Hexamethylene tetramine</td>
<td>SML(T) = 15 mg/kg (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(expressed as Formaldehyde)</td>
</tr>
<tr>
<td>18700</td>
<td>000629-11-8</td>
<td>1,6-Hexanediol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>18820</td>
<td>000592-41-6</td>
<td>1-Hexene</td>
<td>SML = 3 mg/kg</td>
</tr>
<tr>
<td>18867</td>
<td>000123-31-9</td>
<td>Hydroquinone</td>
<td>See ‘1,4-Dihydroxybenzene’</td>
</tr>
<tr>
<td>18880</td>
<td>000099-96-7</td>
<td>p-Hydroxybenzoic acid</td>
<td></td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>(1)</td>
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<td>(4)</td>
</tr>
<tr>
<td>18896</td>
<td>001679-51-2</td>
<td>4-(Hydroxymethyl)-1-cyclohexene</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>18897</td>
<td>016712-64-4</td>
<td>6-Hydroxy-2-naphthalene-carboxylic acid</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>18898</td>
<td>000103-90-2</td>
<td>N-(4-Hydroxyphenyl) acetamide</td>
<td>►M2 SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>19000</td>
<td>000115-11-7</td>
<td>Isobutene</td>
<td></td>
</tr>
<tr>
<td>19060</td>
<td>000109-53-5</td>
<td>Isobutyl vinyl ether</td>
<td></td>
</tr>
<tr>
<td>19110</td>
<td>004098-71-9</td>
<td>1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (26)</td>
</tr>
<tr>
<td>19150</td>
<td>000121-91-5</td>
<td>Isophthalic acid</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>19210</td>
<td>001459-93-4</td>
<td>Isophthalic acid, dimethyl ester</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>19243</td>
<td>000078-79-5</td>
<td>Isoprene</td>
<td>See '2-Methyl-1,3-butadiene'</td>
</tr>
<tr>
<td>19270</td>
<td>000097-65-4</td>
<td>Itaconic acid</td>
<td></td>
</tr>
<tr>
<td>19460</td>
<td>000050-21-5</td>
<td>Lactic acid</td>
<td></td>
</tr>
<tr>
<td>19470</td>
<td>000143-07-7</td>
<td>Lauric acid</td>
<td></td>
</tr>
<tr>
<td>19480</td>
<td>002146-71-6</td>
<td>Lauric acid, vinyl ester</td>
<td></td>
</tr>
<tr>
<td>19490</td>
<td>000947-04-6</td>
<td>Laurolactam</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>19510</td>
<td>011132-73-3</td>
<td>Lignocellulose</td>
<td></td>
</tr>
<tr>
<td>19540</td>
<td>000110-16-7</td>
<td>Maleic acid</td>
<td>SML(T) = 30 mg/kg (4)</td>
</tr>
<tr>
<td>19960</td>
<td>000108-31-6</td>
<td>Maleic anhydride</td>
<td>SML(T) = 30 mg/kg (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(expressed as maleic acid)</td>
<td></td>
</tr>
<tr>
<td>19975</td>
<td>000108-78-1</td>
<td>Melamine</td>
<td>See '2',4,6-triamino-1,3,5-triazine'</td>
</tr>
<tr>
<td>19990</td>
<td>000079-39-0</td>
<td>Methacrylamide</td>
<td>SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>20020</td>
<td>000079-41-4</td>
<td>Methacrylic acid</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>20050</td>
<td>000096-05-9</td>
<td>Methacrylic acid, allyl ester</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>20080</td>
<td>002495-37-6</td>
<td>Methacrylic acid, benzyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>20110</td>
<td>000097-88-1</td>
<td>Methacrylic acid, butyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>20140</td>
<td>002998-18-7</td>
<td>Methacrylic acid, sec-butyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>20170</td>
<td>000585-07-9</td>
<td>Methacrylic acid, tert-butyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>20260</td>
<td>000101-43-9</td>
<td>Methacrylic acid, cyclohexyl ester</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>20410</td>
<td>002082-81-7</td>
<td>Methacrylic acid, diester with 1,4-butenediol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>20440</td>
<td>000097-90-5</td>
<td>Methacrylic acid, diester with ethylene-glycol</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>20530</td>
<td>002867-47-2</td>
<td>Methacrylic acid, 2-(dimethylamino)-ethyl ester</td>
<td>SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>20590</td>
<td>000106-91-2</td>
<td>Methacrylic acid, 2,3-epoxypropyl ester</td>
<td>QMA = 0,02 mg/6 dm&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>20890</td>
<td>000097-63-2</td>
<td>Methacrylic acid, ethyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>21010</td>
<td>000097-86-9</td>
<td>Methacrylic acid, isobutyl ester</td>
<td>►M3 SML(T) = 6 mg/kg (27)</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>(4)</td>
</tr>
<tr>
<td>21100</td>
<td>004655-34-9</td>
<td>Methacrylic acid, isopropyl ester</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21130</td>
<td>000080-62-6</td>
<td>Methacrylic acid, methyl ester</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21190</td>
<td>000868-77-9</td>
<td>Methacrylic acid, monoester with ethylene-glycol</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21280</td>
<td>002177-70-0</td>
<td>Methacrylic acid, phenyl ester</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21340</td>
<td>002210-28-8</td>
<td>Methacrylic acid, propyl ester</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21370</td>
<td>010595-80-9</td>
<td>Methacrylic acid, 2-sulphoethyl ester</td>
<td>QMA = ND (DL = 0,02 mg/6 dm²)</td>
</tr>
<tr>
<td>21400</td>
<td>054276-35-6</td>
<td>Methacrylic acid, sulphopropyl ester</td>
<td>QMA = 0,05 mg/6 dm²</td>
</tr>
<tr>
<td>21460</td>
<td>000760-93-0</td>
<td>Methacrylic anhydride</td>
<td>▶ ▼ M3 SML(T) = 6 mg/kg (7)</td>
</tr>
<tr>
<td>21490</td>
<td>000126-98-7</td>
<td>Methacrylonitrile</td>
<td>SML = ND (DL = 0,020 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>21520</td>
<td>001561-92-8</td>
<td>Methallylsulphonic acid, sodium salt</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>21550</td>
<td>000067-56-1</td>
<td>Methanol</td>
<td></td>
</tr>
<tr>
<td>21640</td>
<td>000078-79-5</td>
<td>2-Methyl-1,3-butadiene</td>
<td>QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>21730</td>
<td>000563-45-1</td>
<td>3-Methyl-1-butene</td>
<td>QMA = 0,006 mg/6 dm². For use only in Polypropylene</td>
</tr>
<tr>
<td>21765</td>
<td>106246-33-7</td>
<td>4,4'-Methylenebis(3-chloro-2,6-diethylaniline)</td>
<td>QMA = 0,05 mg/6 dm²</td>
</tr>
<tr>
<td>21821</td>
<td>000505-65-7</td>
<td>1,4-(Methylenedioxy)butane</td>
<td>See ‘1,4-Butanediol formal’</td>
</tr>
<tr>
<td>21940</td>
<td>000924-42-5</td>
<td>N-Methylolacrylamide</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
</tr>
<tr>
<td>22150</td>
<td>000091-37-2</td>
<td>4-Methyl-1-pentene</td>
<td>▶ ▼ M2 SML = 0,05 mg/kg kg</td>
</tr>
<tr>
<td>22210</td>
<td>000098-83-9</td>
<td>alpha-Methylstylene</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>22331</td>
<td>025513-64-8</td>
<td>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</td>
<td>QMA = 5 mg/6 dm³</td>
</tr>
<tr>
<td>22332</td>
<td>▶ ▼ M2</td>
<td>Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (60)</td>
</tr>
<tr>
<td>22350</td>
<td>000544-63-8</td>
<td>Myristic acid</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>22360</td>
<td>001141-38-4</td>
<td>2,6-Naphthalenedicarboxylic acid</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>22390</td>
<td>000840-65-3</td>
<td>2,6-Naphthalenedicarboxylic acid, dimethyl ester</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>22420</td>
<td>003173-72-6</td>
<td>1,5-Naphthalene diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (60)</td>
</tr>
<tr>
<td>22437</td>
<td>000126-30-7</td>
<td>Neopentylglycol</td>
<td>See ‘2,2-Dimethyl-1,3-propanediol’</td>
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<td>22450</td>
<td>009004-70-0</td>
<td>Nitrocellulose</td>
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<td>22480</td>
<td>000143-08-8</td>
<td>1-Nonanol</td>
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<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<tr>
<td>22550</td>
<td>000498-66-8</td>
<td>Norbornene</td>
<td>See ‘Bicyclo[2.2.1]hept-2-ene’</td>
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<tr>
<td>22570</td>
<td>000112-96-9</td>
<td>Octadecyl isocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (26)</td>
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<tr>
<td>22600</td>
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<td>1-Octanol</td>
<td>SML = 15 mg/kg</td>
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<td>1-Octene</td>
<td>SML = 15 mg/kg</td>
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<tr>
<td>22750</td>
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<td>Oxalic acid</td>
<td>SML(T) = 6 mg/kg</td>
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<tr>
<td>22780</td>
<td>007456-68-0</td>
<td>4,4’-Oxybis(benzenesulphonyl azide)</td>
<td>QMA = 0,05 mg/6 dm³</td>
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<tr>
<td>22800</td>
<td>000057-10-3</td>
<td>Palmitic acid</td>
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<td>22840</td>
<td>000115-77-5</td>
<td>Pentaerythritol</td>
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<td>22870</td>
<td>000071-41-0</td>
<td>1-Pentanol</td>
<td>SML = 5 mg/kg</td>
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<tr>
<td>22900</td>
<td>000109-67-1</td>
<td>1-Pentene</td>
<td>SML = 5 mg/kg</td>
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<tr>
<td>22932</td>
<td>001187-93-5</td>
<td>Perfluoromethyl perfluorovinyl ether</td>
<td>SML = 0,05 mg/kg. Only to be used for anti-stick coatings</td>
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<tr>
<td>22937</td>
<td>001623-05-8</td>
<td>Perfluoropropylperfluorovinyl ether</td>
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<td>000108-95-2</td>
<td>Phenol</td>
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<td>000108-45-2</td>
<td>1,3-Phenylenediamine</td>
<td>SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
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<td>(1,3-Phenylenedioxy)diacetic acid</td>
<td>QMA = 0,05 mg/6 dm³</td>
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<td>See ‘Carbonyl chloride’</td>
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<td>23170</td>
<td>007664-38-2</td>
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<td>Phosphorous acid, triethyl ester</td>
<td>QM = ND (DL = 1 mg/kg in FP)</td>
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<td>See ‘Terephthalic acid’</td>
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<td>Phthalic acid, diallyl ester</td>
<td>SML = ND (DL = 0,01 mg/kg)</td>
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<td>23380</td>
<td>000085-44-9</td>
<td>Phthalic anhydride</td>
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<td>alpha-Pinene</td>
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<td>23547</td>
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<td>Polydimethylsiloxane (Mw &gt; 6 800)</td>
<td>In compliance with the specifications laid down in Annex V</td>
</tr>
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<tr>
<td>23590</td>
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<td>Polyethylene glycol</td>
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</tr>
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<td>23651</td>
<td>025322-69-4</td>
<td>Polyoxyethylene glycol</td>
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<td>000057-55-6</td>
<td>1,2-Propanediol</td>
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</tr>
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<td>000054-63-2</td>
<td>1,3-Propanediol</td>
<td>SML = 0,05 mg/kg</td>
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<td>23800</td>
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<td>1-Propanol</td>
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<td>23860</td>
<td>000123-38-6</td>
<td>Propionaldehyde</td>
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<td>000079-09-4</td>
<td>Propionic acid</td>
<td></td>
</tr>
<tr>
<td>23920</td>
<td>000105-38-4</td>
<td>Propionic acid, vinyl ester</td>
<td>SML(T) = 6 mg/kg (2) (expressed as Acetaldehyde)</td>
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<td>000123-62-6</td>
<td>Propionic anhydride</td>
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</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>23980</td>
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<td>Propylene oxide</td>
<td>QM = 1 mg/kg in FP</td>
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<td>24051</td>
<td>000120-80-9</td>
<td>Pyrocatechol</td>
<td>See ‘1,2-Dihydroxybenzene’</td>
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<td>24057</td>
<td>000089-32-7</td>
<td>Pyromellitic anhydride</td>
<td>SML = 0,05 mg/kg (expressed as Pyromellitic acid)</td>
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<tr>
<td>24070</td>
<td>073138-82-6</td>
<td>Resin acids and Rosin acids</td>
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<tr>
<td>24072</td>
<td>000108-46-3</td>
<td>Resorcinol</td>
<td>See ‘1,3-Dihydroxybenzene’</td>
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<td>24073</td>
<td>000101-90-6</td>
<td>Resorcinol diglycidyl ether</td>
<td>QMA = 0,005 mg/6 dm². Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer.</td>
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<td>24100</td>
<td>008050-09-7</td>
<td>Rosin</td>
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</tr>
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<td>24130</td>
<td>008050-09-7</td>
<td>Rosin gum</td>
<td>See ‘Rosin’</td>
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<tr>
<td>24160</td>
<td>008052-10-6</td>
<td>Rosin tall oil</td>
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</tr>
<tr>
<td>24190</td>
<td>►M3 00805-04-7</td>
<td>Rosin wood</td>
<td>►M3 See ‘Rosin’ (Reference No 24100) ◄</td>
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<td>24250</td>
<td>009006-04-6</td>
<td>Rubber, natural</td>
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<td>000069-72-7</td>
<td>Salicylic acid</td>
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<td>Sebacic acid</td>
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<td>002561-88-8</td>
<td>Sebacic anhydride</td>
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<td>24475</td>
<td>001313-82-2</td>
<td>Sodium sulphide</td>
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<td>000050-70-4</td>
<td>Sorbitol</td>
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<td>008001-22-7</td>
<td>Soybean oil</td>
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<td>009005-25-8</td>
<td>Starch, edible</td>
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</tr>
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<td>000057-11-4</td>
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<td>24610</td>
<td>000100-42-5</td>
<td>Styrene</td>
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<td>24760</td>
<td>026914-43-2</td>
<td>Styrenesuphonic acid</td>
<td>SML = 0,05 mg/kg</td>
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<tr>
<td>24820</td>
<td>000110-15-6</td>
<td>Succinic acid</td>
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<td>24850</td>
<td>000108-30-5</td>
<td>Succinic anhydride</td>
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<td>24880</td>
<td>000057-50-1</td>
<td>Sucrose</td>
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<tr>
<td>24887</td>
<td>006362-79-4</td>
<td>5-Sulphoisophthalic acid, monosodium salt</td>
<td>SML = 5 mg/kg</td>
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<tr>
<td>24888</td>
<td>003965-55-7</td>
<td>5-Sulphoisophthalic acid, monosodium salt, dimethyl ester</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>▼M3</td>
<td>24903</td>
<td>068425-17-2</td>
<td>Syrups, hydrolysed starch, hydrogenated</td>
</tr>
<tr>
<td>▼C1</td>
<td>24910</td>
<td>000100-21-0</td>
<td>Terephthalic acid</td>
</tr>
<tr>
<td>24940</td>
<td>000100-20-9</td>
<td>Terephthalic acid dichloride</td>
<td>SML(T) = 7,5 mg/kg (expressed as Terephthalic acid)</td>
</tr>
<tr>
<td>24970</td>
<td>000120-61-6</td>
<td>Terephthalic acid, dimethyl ester</td>
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</tr>
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<td>25080</td>
<td>001120-36-1</td>
<td>1-Tetradecene</td>
<td>SML = 0,05 mg/kg</td>
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<td>25090</td>
<td>000112-60-7</td>
<td>Tetraethylenglycol</td>
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<td>25120</td>
<td>000116-14-3</td>
<td>Tetrafluoroethylene</td>
<td>SML = 0,05 mg/kg</td>
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<td>25150</td>
<td>000109-99-9</td>
<td>Tetrahydrofuran</td>
<td>SML = 0,6 mg/kg</td>
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<tr>
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<td>Restrictions and/or specifications</td>
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<td>25180</td>
<td>000102-60-3</td>
<td>N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine</td>
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<tr>
<td>25210</td>
<td>000584-84-9</td>
<td>2,4-Toluene diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (26)</td>
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<td>25240</td>
<td>000091-08-7</td>
<td>2,6-Toluene diisocyanate</td>
<td>QM(T) = 1 mg/kg (expressed as NCO) (26)</td>
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<tr>
<td>25360</td>
<td>026747-90-0</td>
<td>2,4-Toluene diisocyanate dimer</td>
<td>QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)</td>
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<tr>
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<td>—</td>
<td>Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester</td>
<td>QMA = 0.05 mg/6 dm²</td>
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<td>25385</td>
<td>000102-70-5</td>
<td>Triallyamine</td>
<td>In compliance with the specifications laid down in Annex V</td>
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<td>2,4,6-Triamino-1,3,5-triazine</td>
<td>SML = 30 mg/kg</td>
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<td>026896-48-0</td>
<td>Tricyclodecanedimethanol</td>
<td>SML = 0.05 mg/kg</td>
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<td>000112-27-6</td>
<td>Triethyleneglycol</td>
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<tr>
<td>25540</td>
<td>000528-44-9</td>
<td>Trimeellitic acid</td>
<td>SML(T) = 5 mg/kg (19)</td>
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<tr>
<td>25550</td>
<td>000552-30-7</td>
<td>Trimellitic anhydride</td>
<td>SML(T) = 5 mg/kg (19)</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>(expressed as trimeellitic acid)</td>
</tr>
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<td>25600</td>
<td>000077-99-6</td>
<td>1,1,1-Trimethylolpropane</td>
<td>SML = 6 mg/kg</td>
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<td>25840</td>
<td>003290-92-4</td>
<td>1,1,1-Trimethylolpropane trimethacrylate</td>
<td>SML = 0.05 mg/kg</td>
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<td>25900</td>
<td>000110-88-3</td>
<td>Trioxane</td>
<td>SML = 0.05 mg/kg</td>
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<td>25910</td>
<td>024800-44-0</td>
<td>Tripropyleneglycol</td>
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<tr>
<td>25927</td>
<td>027955-94-8</td>
<td>1,1,1-Tris(4-hydroxyphenol)ethane</td>
<td>QM = 0.5 mg/kg in FP. For use only in polycarbonates</td>
</tr>
<tr>
<td>25960</td>
<td>000057-13-6</td>
<td>Urea</td>
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<tr>
<td>26110</td>
<td>000075-35-4</td>
<td>Vinylidene chloride</td>
<td>QM = 5 mg/kg in FP or SML = ND (DL = 0.05 mg/kg)</td>
</tr>
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<td>26140</td>
<td>000075-38-7</td>
<td>Vinylidene fluoride</td>
<td>SML = 5 mg/kg</td>
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<td>26155</td>
<td>001072-63-5</td>
<td>1-Vinylimidazole</td>
<td>QM = 5 mg/kg in FP</td>
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<td>26170</td>
<td>003195-78-6</td>
<td>N-Vinyl-N-methylacetamide</td>
<td>QM = 2 mg/kg in FP</td>
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<td>26320</td>
<td>002768-02-7</td>
<td>Vinyltrimethoxysilane</td>
<td>QM = 5 mg/kg in FP</td>
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<td>26360</td>
<td>007732-18-5</td>
<td>Water</td>
<td>In compliance with Directive 98/83/EC</td>
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**Notes:**
- QM(T) = 1 mg/kg (expressed as NCO) (26)
- QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)
- SML(T) = 5 mg/kg (19)
- SML = ND (DL = 0.05 mg/kg)
- QM = 0.5 mg/kg in FP. For use only in polycarbonates.
## Section B

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

<table>
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<tr>
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<th>Restrictions and/or specifications</th>
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<td>▼M3</td>
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<td>▼C1</td>
<td>13050</td>
<td>00528-44-9 1,2,4-Benzene-tricarboxylic acid</td>
<td>See ‘Trimellitic acid’</td>
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<td>▼M2</td>
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<td></td>
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<td>▼M3</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>▼C1</td>
<td>15730</td>
<td>00077-73-6 Dicyclopentadiene</td>
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<td>▼M2</td>
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<tr>
<td>▼C1</td>
<td>18370</td>
<td>00592-45-0 1,4-Hexadiene</td>
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<td>▼M2</td>
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</tr>
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<tr>
<td>▼C1</td>
<td>21970</td>
<td>00923-02-4 N-Methylolmethacrylamide</td>
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<tr>
<td>▼C1</td>
<td>26230</td>
<td>00088-12-0 Vinilpyrrolidone</td>
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</table>


ANNEX III

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

GENERAL INTRODUCTION

1. This Annex contains the list of:

(a) substances which are incorporated into plastics to achieve a technical
effect in the finished product, 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
copolymers as the main structural component of finished materials and articles.
It includes also substances which may be added to the medium in which poly-
merisation occurs.

The list does not include:

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

(b) colorants;

(c) solvents.

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.

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

(a) substances which could be present in the finished product such as:

— impurities in the substances used,

— reaction intermediates,

— decomposition products;

(b) mixtures of the authorised substances.

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

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

5. The list contains the following information:

— column 1 (Ref. No): the EEC packaging material reference number of the
substances on the list,

— column 2 (CAS No): the CAS (Chemical Abstracts Service) registry
number,

— column 3 (Name): the chemical name,
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

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>CAS No</th>
<th>Name</th>
<th>Restrictions and/or specifications</th>
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<td>(3)</td>
</tr>
<tr>
<td>30000</td>
<td>0000064-19-7</td>
<td>Acetic acid</td>
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<tr>
<td>30045</td>
<td>000123-86-4</td>
<td>Acetic acid, butyl ester</td>
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</tr>
<tr>
<td>30080</td>
<td>004180-12-5</td>
<td>Acetic acid, copper salt</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>M3</td>
<td>SML(T) = 5 mg/kg (expressed as Copper)</td>
</tr>
<tr>
<td>30140</td>
<td>000141-78-6</td>
<td>Acetic acid, ethyl ester</td>
<td></td>
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<tr>
<td>30280</td>
<td>000108-24-7</td>
<td>Acetic anhydride</td>
<td></td>
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<tr>
<td>30295</td>
<td>000067-64-1</td>
<td>Acetone</td>
<td></td>
</tr>
<tr>
<td>▼ M3</td>
<td>30340</td>
<td>330198-91-9</td>
<td>12-(Acetoxy)stearic acid, 2,3-bis(acetoxy) propyl ester</td>
</tr>
<tr>
<td>▼ C1</td>
<td>30370</td>
<td>—</td>
<td>Acetylaetic acid, salts</td>
</tr>
<tr>
<td>▼ M3</td>
<td>30401</td>
<td>—</td>
<td>Acetylated mono- and diglycerides of fatty acids</td>
</tr>
<tr>
<td>▼ C1</td>
<td>30610</td>
<td>—</td>
<td>Acids, C1-C20, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occuring levels are included)</td>
</tr>
<tr>
<td></td>
<td>30612</td>
<td>—</td>
<td>Acids, C1-C20, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters</td>
</tr>
<tr>
<td></td>
<td>30960</td>
<td>—</td>
<td>Acids, aliph., monocarb. (C1-C2), esters with polyglycerol</td>
</tr>
<tr>
<td></td>
<td>31328</td>
<td>—</td>
<td>Acids, fatty, from animal or vegetable food fats and oils</td>
</tr>
<tr>
<td></td>
<td>31530</td>
<td>123968-25-2</td>
<td>Acrylic acid, 2,4-di-tet-pentyl-6-(1-(3,5-di-tet-pentyl-2-hydroxyphenyl)ethyl)phenyl ester</td>
</tr>
<tr>
<td>▼ M3</td>
<td>31542</td>
<td>174254-23-0</td>
<td>Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C12-C14 alkyl esters</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>------------------------------------------------</td>
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<tr>
<td>31730</td>
<td>000124-04-9</td>
<td>Adipic acid</td>
<td></td>
</tr>
<tr>
<td>33120</td>
<td>—</td>
<td>Alcohols, aliph, monoh., sat., linear, primary (C&lt;sub&gt;4&lt;/sub&gt;-C&lt;sub&gt;24&lt;/sub&gt;)</td>
<td></td>
</tr>
<tr>
<td>33350</td>
<td>009005-32-7</td>
<td>Alginic acid</td>
<td></td>
</tr>
<tr>
<td>33801</td>
<td>—</td>
<td>n-Alkyl(C&lt;sub&gt;10&lt;/sub&gt;-C&lt;sub&gt;13&lt;/sub&gt;)benzenesulphonic acid</td>
<td>SML = 30 mg/kg</td>
</tr>
<tr>
<td>34240</td>
<td>—</td>
<td>Alkyl(C&lt;sub&gt;10&lt;/sub&gt;-C&lt;sub&gt;20&lt;/sub&gt;)sulphonic acid, esters with phenols</td>
<td>SML = 6 mg/kg. Authorised until 1 January 2002</td>
</tr>
<tr>
<td>34281</td>
<td>—</td>
<td>Alkyl(C&lt;sub&gt;10&lt;/sub&gt;-C&lt;sub&gt;24&lt;/sub&gt;)sulphuric acids, linear, primary with an even number of carbon atoms</td>
<td></td>
</tr>
<tr>
<td>34475</td>
<td>—</td>
<td>Aluminum calcium hydroxide phosphate, hydrate</td>
<td></td>
</tr>
<tr>
<td>34480</td>
<td>—</td>
<td>Aluminium fibers, flakes and powders</td>
<td></td>
</tr>
<tr>
<td>34560</td>
<td>021645-51-2</td>
<td>Aluminium hydroxide</td>
<td></td>
</tr>
<tr>
<td>34690</td>
<td>011097-59-9</td>
<td>Aluminium magnesium carbonate hydroxide</td>
<td></td>
</tr>
<tr>
<td>34720</td>
<td>001344-28-1</td>
<td>Aluminium oxide</td>
<td></td>
</tr>
<tr>
<td>34850</td>
<td>143925-92-2</td>
<td>Amines, bis(hydrogenated tallow alkyl) oxidised</td>
<td>QM = For use only: (a) in polyolefines at 0,1 % (w/w) but not in LDPE when it is in contact with foods for which the Directive 85/572/EEC establishes a reduction factor less than 3; (b) in PET at 0,25 % (w/w) in contact with foods other of those for which the simulant D is laid down in Directive 85/572/EEC 85/572/EEC</td>
</tr>
<tr>
<td>34895</td>
<td>000088-68-6</td>
<td>2-Aminobenzamide</td>
<td>SML = 0,05 mg/kg. To be used only for PET for water and beverages</td>
</tr>
<tr>
<td>35120</td>
<td>013560-49-1</td>
<td>3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether</td>
<td></td>
</tr>
<tr>
<td>35160</td>
<td>006642-31-5</td>
<td>6-Amino-1,3-dimethyluracil</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>35170</td>
<td>000141-43-5</td>
<td>2-Aminoethanol</td>
<td>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</td>
</tr>
<tr>
<td>35284</td>
<td>000111-41-1</td>
<td>N-(2-aminoethyl)ethanolamine</td>
<td>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.</td>
</tr>
<tr>
<td>35320</td>
<td>007664-41-7</td>
<td>Ammonia</td>
<td></td>
</tr>
<tr>
<td>35440</td>
<td>001214-97-9</td>
<td>Ammonium bromide</td>
<td></td>
</tr>
<tr>
<td>35600</td>
<td>001336-21-6</td>
<td>Ammonium hydroxide</td>
<td></td>
</tr>
<tr>
<td>35840</td>
<td>000506-30-9</td>
<td>Arachidic acid</td>
<td></td>
</tr>
<tr>
<td>35845</td>
<td>007771-44-0</td>
<td>Arachidonic acid</td>
<td></td>
</tr>
<tr>
<td>Ref. No</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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</tr>
<tr>
<td>36000</td>
<td>000050-81-7</td>
<td>Ascorbic acid</td>
<td></td>
</tr>
<tr>
<td>36080</td>
<td>000137-66-6</td>
<td>Ascorbyl palmitate</td>
<td></td>
</tr>
<tr>
<td>36160</td>
<td>010605-09-1</td>
<td>Ascorbyl stearate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>000123-77-3</td>
<td>Azodicarbonamide</td>
<td>For use only as blowing agent. Use prohibited as from 2 August 2005.</td>
</tr>
<tr>
<td>36840</td>
<td>012007-55-5</td>
<td>Barium tetraborate</td>
<td>SML(T) = 1 mg/kg expressed as Barium ((\text{B}^2)) and SML (T) = 6 mg/kg ((\text{B}^6)) expressed as Boron without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L330, 5.12.1998, p. 32).</td>
</tr>
<tr>
<td>36880</td>
<td>008012-89-3</td>
<td>Beeswax</td>
<td></td>
</tr>
<tr>
<td>36960</td>
<td>003061-75-4</td>
<td>Behenamide</td>
<td></td>
</tr>
<tr>
<td>37040</td>
<td>000112-85-6</td>
<td>Behenic acid</td>
<td></td>
</tr>
<tr>
<td>37280</td>
<td>001302-78-9</td>
<td>Bentonite</td>
<td></td>
</tr>
<tr>
<td>37360</td>
<td>000100-52-7</td>
<td>Benzaldehyde</td>
<td>In compliance with note 9 in Annex VI</td>
</tr>
<tr>
<td>37600</td>
<td>000065-85-0</td>
<td>Benzoic acid</td>
<td></td>
</tr>
<tr>
<td>37680</td>
<td>000136-60-7</td>
<td>Benzoic acid, butyl ester</td>
<td></td>
</tr>
<tr>
<td>37840</td>
<td>000093-89-0</td>
<td>Benzoic acid, ethyl ester</td>
<td></td>
</tr>
<tr>
<td>38080</td>
<td>000093-58-3</td>
<td>Benzoic acid, methyl ester</td>
<td></td>
</tr>
<tr>
<td>38160</td>
<td>002315-68-6</td>
<td>Benzoic acid, propyl ester</td>
<td></td>
</tr>
<tr>
<td>38510</td>
<td>136504-96-6</td>
<td>1,2-Bis(3-aminopropyl)ethylendiamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>38515</td>
<td>001533-45-5</td>
<td>4,4’-Bis(2-benzoxazolyl)stilbene</td>
<td>SML = 0,05 mg/kg ((\text{B}^2))</td>
</tr>
<tr>
<td>38810</td>
<td>080693-00-1</td>
<td>Bis(2,6-di-tart-butyl-4-methylphenyl) pentaerythritol diphosphate</td>
<td>SML = 5 mg/kg (sum of phosphate and phosphate)</td>
</tr>
<tr>
<td>38840</td>
<td>154862-43-8</td>
<td>Bis(2,4-dicumylphenyl)pentaerythritol-diphosphate</td>
<td>SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)).</td>
</tr>
<tr>
<td>38879</td>
<td>135861-56-2</td>
<td>Bis(3,4-dimethylbenzylidene)orbotol</td>
<td></td>
</tr>
<tr>
<td>38950</td>
<td>079072-96-1</td>
<td>Bis(4-ethylbenzylidene)orbotol</td>
<td></td>
</tr>
<tr>
<td>39200</td>
<td>006200-40-4</td>
<td>Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxymethylammonium chloride</td>
<td>SML = 1,8 mg/kg</td>
</tr>
<tr>
<td>39680</td>
<td>000080-05-7</td>
<td>2,2-Bis(4-hydroxyphenyl)propene</td>
<td>SML(T) = 0,6 mg/kg ((\text{B}^6))</td>
</tr>
<tr>
<td>39815</td>
<td>182121-12-6</td>
<td>9,9-Bis(methoxymethyl)fluorene</td>
<td>QMA = 0,05 mg/6 dm(^3)</td>
</tr>
<tr>
<td>39890</td>
<td>087826-41-3</td>
<td>Bis(methylbenzylidene)orbotol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>069158-41-4</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>054686-97-4</td>
<td></td>
<td></td>
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<td>081541-12-0</td>
<td></td>
<td></td>
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<tr>
<td>39925</td>
<td>129228-21-3</td>
<td>3,3-Bis(methoxymethyl)-2,5-dimethylhexane</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
</tr>
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<td>---------</td>
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<td>-----------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>40120</td>
<td>068951-50-8</td>
<td>Bis(polyethyleneglycol)hydroxymethylphosphonate</td>
<td>SML = 0.6 mg/kg</td>
</tr>
<tr>
<td>40400</td>
<td>010043-11-5</td>
<td>Boron nitride</td>
<td></td>
</tr>
<tr>
<td>40570</td>
<td>000106-97-8</td>
<td>Butane</td>
<td></td>
</tr>
<tr>
<td>40580</td>
<td>000110-63-4</td>
<td>1,4-Butanediol</td>
<td>M3 SML(T) = 5 mg/kg (24)</td>
</tr>
<tr>
<td>41040</td>
<td>005743-36-2</td>
<td>Calcium butyrate</td>
<td></td>
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<tr>
<td>41120</td>
<td>010043-52-4</td>
<td>Calcium chloride</td>
<td></td>
</tr>
<tr>
<td>41280</td>
<td>001305-62-0</td>
<td>Calcium hydroxide</td>
<td></td>
</tr>
<tr>
<td>41520</td>
<td>001305-78-8</td>
<td>Calcium oxide</td>
<td></td>
</tr>
<tr>
<td>41600</td>
<td>012004-14-7</td>
<td>Calcium sulphoaluminate</td>
<td></td>
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<tr>
<td>41680</td>
<td>000076-22-2</td>
<td>Camphor</td>
<td>In compliance with note 9 in Annex VI</td>
</tr>
<tr>
<td>41760</td>
<td>008006-44-8</td>
<td>Candelilla wax</td>
<td></td>
</tr>
<tr>
<td>41840</td>
<td>000105-60-2</td>
<td>Caprolactam</td>
<td>SML(T) = 15 mg/kg (5)</td>
</tr>
<tr>
<td>41960</td>
<td>000124-07-2</td>
<td>Caprylic acid</td>
<td></td>
</tr>
<tr>
<td>42160</td>
<td>000124-38-9</td>
<td>Carbon dioxide</td>
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</tr>
<tr>
<td>42320</td>
<td>007492-68-4</td>
<td>Carbonic acid, copper salt</td>
<td>M3 SML(T) = 5 mg/kg (7)</td>
</tr>
<tr>
<td>42500</td>
<td>—</td>
<td>Carbonic acid, salts</td>
<td></td>
</tr>
<tr>
<td>42640</td>
<td>009000-11-7</td>
<td>Carboxymethylcellulose</td>
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<tr>
<td>42720</td>
<td>008015-86-9</td>
<td>Carnauba wax</td>
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<td>42800</td>
<td>009000-71-9</td>
<td>Casein</td>
<td></td>
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<td>42880</td>
<td>008001-79-4</td>
<td>Castor oil</td>
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<tr>
<td>42960</td>
<td>064147-40-6</td>
<td>Castor oil, dehydrated</td>
<td></td>
</tr>
<tr>
<td>43200</td>
<td>—</td>
<td>Castor oil, mono- and diglycerides</td>
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</tr>
<tr>
<td>43280</td>
<td>009004-34-6</td>
<td>Cellulose</td>
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<td>43300</td>
<td>009004-36-8</td>
<td>Cellulose acetate butyrate</td>
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<td>43360</td>
<td>068442-85-3</td>
<td>Cellulose, regenerated</td>
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<td>43440</td>
<td>008001-75-0</td>
<td>Ceresin</td>
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<tr>
<td>43480</td>
<td>064365-11-3</td>
<td>Charcoal, activated</td>
<td>In compliance with the specifications laid down in Annex V, Part B</td>
</tr>
<tr>
<td>43515</td>
<td>—</td>
<td>Chlorides of choline esters of coconut oil fatty acids</td>
<td>QMA = 0.9 mg/6 dm²</td>
</tr>
<tr>
<td>44160</td>
<td>000077-92-9</td>
<td>Citric acid</td>
<td></td>
</tr>
<tr>
<td>44640</td>
<td>000077-93-0</td>
<td>Citric acid, triethyl ester</td>
<td></td>
</tr>
<tr>
<td>45195</td>
<td>007787-70-4</td>
<td>Copper bromide</td>
<td>M3 SML(T) = 5 mg/kg (7)</td>
</tr>
<tr>
<td>45200</td>
<td>001335-23-5</td>
<td>Copper iodide</td>
<td>M3 SML(T) = 5 mg/kg (7)</td>
</tr>
<tr>
<td>45280</td>
<td>—</td>
<td>Cotton fibers</td>
<td></td>
</tr>
<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>45450</td>
<td>068610-51-5</td>
<td>p-Cresol-dicyclopentadiene-isobutylene, copolymer</td>
<td>▶ M2 SML = 5 mg/kg ◀</td>
</tr>
<tr>
<td>45560</td>
<td>014464-46-1</td>
<td>Cristobalite</td>
<td></td>
</tr>
<tr>
<td>45600</td>
<td>003724-65-0</td>
<td>Crotonic acid</td>
<td>QMA(T) = 0.05 mg/6 dm² (1)</td>
</tr>
<tr>
<td>45640</td>
<td>005232-99-5</td>
<td>2-Cyano-3,3-diphenylacrylic acid, ethyl ester</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>45760</td>
<td>000108-91-8</td>
<td>Cyclohexylamine</td>
<td></td>
</tr>
<tr>
<td>45920</td>
<td>009000-16-2</td>
<td>Dammar</td>
<td></td>
</tr>
<tr>
<td>45940</td>
<td>000334-48-5</td>
<td>n-Decanoic acid</td>
<td></td>
</tr>
<tr>
<td>46070</td>
<td>010016-20-3</td>
<td>alpha-Dextrin</td>
<td></td>
</tr>
<tr>
<td>46080</td>
<td>007585-39-9</td>
<td>beta-Dextrin</td>
<td></td>
</tr>
<tr>
<td>46375</td>
<td>061790-53-2</td>
<td>Diatomaceous earth</td>
<td></td>
</tr>
<tr>
<td>46380</td>
<td>068855-54-9</td>
<td>Diatomaceous earth, soda ash flux-calcined</td>
<td></td>
</tr>
<tr>
<td>46800</td>
<td>032647-67-9</td>
<td>Dibenzyldiene sorbitol</td>
<td></td>
</tr>
<tr>
<td>46700</td>
<td>—</td>
<td>5,7-di-tert-Butyl-3-(3,4- and 2,3-dimethyl-phenyl)-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)</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>46720</td>
<td>004130-42-1</td>
<td>2,6-Di-tert-butyl-4-ethylphenol</td>
<td>QMA = 4.8 mg/6 dm²</td>
</tr>
<tr>
<td>46790</td>
<td>004221-80-1</td>
<td>3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester</td>
<td></td>
</tr>
<tr>
<td>46800</td>
<td>067845-93-6</td>
<td>3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester</td>
<td></td>
</tr>
<tr>
<td>46870</td>
<td>003135-18-0</td>
<td>3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester</td>
<td></td>
</tr>
<tr>
<td>46880</td>
<td>065140-91-2</td>
<td>3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>47210</td>
<td>026427-07-6</td>
<td>Dibutylthiostannic acid polymer [= Thiobis(butyl-tin sulphide), polymer]</td>
<td>In compliance with the specifications laid down in Annex V.</td>
</tr>
<tr>
<td>47440</td>
<td>000461-58-5</td>
<td>Dicyanodiamide</td>
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<td>47540</td>
<td>027458-90-8</td>
<td>Di-tert-dodecyl disulphide</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>47680</td>
<td>000111-46-6</td>
<td>Diethyleneglycol</td>
<td>SML(T) = 30 mg/kg (1')</td>
</tr>
<tr>
<td>48460</td>
<td>000075-37-6</td>
<td>1,1-Difluoroethane</td>
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<tr>
<td>48620</td>
<td>000123-31-9</td>
<td>1,4-Dihydroxybenzene</td>
<td>SML = 0.6 mg/kg</td>
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<tr>
<td>48720</td>
<td>000611-99-4</td>
<td>4,4'-Dihydroxybenzophenone</td>
<td>SML(T) = 6 mg/kg (1')</td>
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<td>49485</td>
<td>134701-20-5</td>
<td>2,4-Dimethyl-6-(1-methylpentadecyl)phenol</td>
<td>SML = 1 mg/kg</td>
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<tr>
<td>49540</td>
<td>000067-68-5</td>
<td>Dimethyl sulphoxide</td>
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<tr>
<td>51200</td>
<td>000126-58-9</td>
<td>Dipentaerythritol</td>
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<td>51700</td>
<td>147315-50-2</td>
<td>2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol</td>
<td>SML = 0.05 mg/kg</td>
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<tr>
<td>51760</td>
<td>025265-71-8</td>
<td>Dipropylene glycol</td>
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<td>52640</td>
<td>016389-88-1</td>
<td>Dolomite</td>
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<td>52645</td>
<td>010436-08-5</td>
<td>cis-11-Eicosenamide</td>
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<td>52720</td>
<td>000112-84-5</td>
<td>Erucamide</td>
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<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>52730</td>
<td>000112-86-7</td>
<td>Erucic acid</td>
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<td>Ethanol</td>
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<td>53270</td>
<td>037205-99-5</td>
<td>Ethylcarboxymethylcellulose</td>
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<td>53280</td>
<td>009004-57-3</td>
<td>Ethylcellulose</td>
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<tr>
<td>53360</td>
<td>000110-31-6</td>
<td>N,N'-Ethylenebisoleamide</td>
<td>▶ <strong>M3</strong> SML(T) = 5 mg/kg (<strong>ρ</strong>) (expressed as Copper) ◀</td>
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<tr>
<td>53440</td>
<td>005518-18-3</td>
<td>N,N'-Ethylenebispalmitamide</td>
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<td>000110-30-5</td>
<td>N,N'-Ethylenebisstearamide</td>
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<td>000060-00-4</td>
<td>Ethylenediaminetaacetic acid</td>
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<td>054453-03-1</td>
<td>Ethylenediaminetaacetic acid, copper salt</td>
<td>▶ <strong>M3</strong> SML(T) = 30 mg/kg (<strong>ρ</strong>)</td>
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<td>000107-21-1</td>
<td>Ethyleneglycol</td>
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<td>54005</td>
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<td>Ethylene-N-palmitamide-N'-stearamide</td>
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<td>Ethylhydroxyethylcellulose</td>
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<td>118337-09-0</td>
<td>2,2′-Ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite</td>
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<td>54450</td>
<td>—</td>
<td>Fats and oils, from animal or vegetable food sources</td>
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<tr>
<td>54480</td>
<td>—</td>
<td>Fats and oils, hydrogenated, from animal or vegetable food sources</td>
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<td>54930</td>
<td>025359-91-5</td>
<td>Formaldehyde-1-naphthol, copolymer [=poly(1-hydroxynaphthylmethane)]</td>
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<td>55040</td>
<td>000064-18-6</td>
<td>Formic acid</td>
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<td>55120</td>
<td>000110-17-8</td>
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<td>009000-70-8</td>
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<td>55520</td>
<td>—</td>
<td>Glass fibers</td>
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<td>55600</td>
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<td>Glass microballs</td>
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<td>Glutaric acid</td>
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<td>099880-64-5</td>
<td>Glycerol dibehenate</td>
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<td>56360</td>
<td>—</td>
<td>Glycerol, esters with acetic acid</td>
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<td>56486</td>
<td>—</td>
<td>Glycerol, esters with acids, aliph., sat., linear, with an even number of carbon atoms (C_12-18) and with acids, aliph., unsat., linear, with an even number of carbon atoms (C_16-18)</td>
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<td>56487</td>
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<td>Glycerol, esters with butyric acid</td>
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<td>Glycerol, esters with erucic acid</td>
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<td>56495</td>
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<td>Glycerol, esters with 12-hydroxystearic acid</td>
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<td>56500</td>
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<td>Glycerol, esters with laurie acid</td>
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<td>56510</td>
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<td>Glycerol, esters with linoleic acid</td>
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<td>56520</td>
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<td>Glycerol, esters with myristic acid</td>
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<td>Glycerol, esters with nonanoic acid</td>
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<td>Glycerol, esters with oleic acid</td>
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<td>Glycerol, esters with palmitic acid</td>
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<td>Ref. No</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>Glycerol, esters with propionic acid</td>
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<td>Glycerol monooleate, ester with ascorbic acid</td>
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<td>57120</td>
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<td>Glycerol monooleate, ester with citric acid</td>
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<td>57200</td>
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<td>Glycerol monopalmitate, ester with ascorbic acid</td>
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<td>57280</td>
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<td>Glycerol monopalmitate, ester with citric acid</td>
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<td>57600</td>
<td>—</td>
<td>Glycerol monostearate, ester with ascorbic acid</td>
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<td>57680</td>
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<td>Glycerol monostearate, ester with citric acid</td>
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<td>Glycerol triheptanoate</td>
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<td>Gum arabic</td>
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<td>Heptanoic acid</td>
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<td>Hexamethylenetetramine</td>
<td>SML(T) = 15 mg/kg (19) (expressed as Formaldehyde)</td>
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<td>Hexanoic acid</td>
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<td>Hydrotalcite</td>
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<td>000120-47-8</td>
<td>4-Hydroxybenzoic acid, ethyl ester</td>
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<td>60180</td>
<td>004191-73-5</td>
<td>4-Hydroxybenzoic acid, isopropyl ester</td>
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<td>000099-76-3</td>
<td>4-Hydroxybenzoic acid, methyl ester</td>
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<td>000094-13-3</td>
<td>4-Hydroxybenzoic acid, propyl ester</td>
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<td>60480</td>
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<td>2-(2-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole</td>
<td>SML(T) = 30 mg/kg (20)</td>
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<td>60560</td>
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<td>Ref. No</td>
<td>CAS No</td>
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<td>Restrictions and/or specifications</td>
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<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
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<td>001332-37-2</td>
<td>Iron oxide</td>
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<td>62245</td>
<td>012751-22-3</td>
<td>Iron phosphide</td>
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<td>For PET polymers and copolymers only</td>
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<td>62450</td>
<td>000078-78-4</td>
<td>Isopentane</td>
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<td>62640</td>
<td>008001-39-6</td>
<td>Japan wax</td>
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<td>001332-58-7</td>
<td>Kaolin</td>
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<td>Kaolin, calcined</td>
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<td>62960</td>
<td>000050-21-5</td>
<td>Lactic acid</td>
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<td>001138-22-7</td>
<td>Lactic acid, butyl ester</td>
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<td>Lauric acid</td>
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<td>Lecithin</td>
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<td>Lysine, salts</td>
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<td>001309-42-8</td>
<td>Magnesium hydroxide</td>
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<td>001309-48-4</td>
<td>Magnesium oxide</td>
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<td>Maleic acid</td>
<td>SML(T) = 30 mg/kg (*)</td>
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<td>▼M3</td>
<td>64990</td>
<td>025736-61-2</td>
<td>Maleic anhydride-styrene, copolymer, sodium salt</td>
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<td>In compliance with specifications laid down in Annex V</td>
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<td>▼C1</td>
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<td>Malic acid</td>
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<td>000087-78-5</td>
<td>Mannitol</td>
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<td>65920</td>
<td>066822-60-4</td>
<td>N-Methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers</td>
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<tr>
<td>66200</td>
<td>037206-01-2</td>
<td>Methylcarboxymethylcellulose</td>
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<td>009004-67-5</td>
<td>Methylcellulose</td>
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<tr>
<td>66560</td>
<td>004066-02-8</td>
<td>2,2’-Methylenebis(4-methyl-6-cyclohexyl-phenol) SML(T) = 3 mg/kg (*)</td>
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<td>66580</td>
<td>000077-62-3</td>
<td>2,2’-Methylenebis(4-methyl-6-(1-methyclohexyl)phenol) SML(T) = 3 mg/kg (*)</td>
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<td>009004-59-5</td>
<td>Methylcellulose</td>
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<td>Methylhydroxymethylcellulose</td>
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<td>009004-65-3</td>
<td>Methylhydroxypropylcellulose</td>
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<td>66755</td>
<td>002682-20-4</td>
<td>2-Methyl-4-isothiazolin-3-one SML = ND (DL = 0.02 mg/kg, analytical tolerance included)</td>
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<td>66905</td>
<td>000872-50-4</td>
<td>N-Methylpyrrolidone</td>
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<td>66930</td>
<td>068554-70-1</td>
<td>Methylsilsequioxane</td>
<td>Residual monomer in methylsilsequioxane: &lt; 1 mg methyltrimethoxysilane/kg of methylsilsequioxane</td>
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<td>▼C1</td>
<td>67120</td>
<td>012001-26-2</td>
<td>Mica</td>
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<td>CAS No</td>
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<td>Restrictions and/or specifications</td>
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<td>--------</td>
<td>----------------------------------------------------------------------</td>
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<td>67155</td>
<td>—</td>
<td>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)</td>
<td>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</td>
</tr>
<tr>
<td>67180</td>
<td>—</td>
<td>Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester</td>
<td>SML = 5 mg/kg (1)</td>
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<td>67200</td>
<td>001317-33-5</td>
<td>Molybdenum disulphide</td>
<td></td>
</tr>
<tr>
<td>67840</td>
<td>—</td>
<td>Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol</td>
<td></td>
</tr>
<tr>
<td>67850</td>
<td>008002-53-7</td>
<td>Montan wax</td>
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<tr>
<td>67891</td>
<td>000544-63-8</td>
<td>Myristic acid</td>
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<tr>
<td>68040</td>
<td>003333-62-8</td>
<td>7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin</td>
<td></td>
</tr>
<tr>
<td>68078</td>
<td>027253-31-2</td>
<td>Neodecanoic acid, cobalt salt</td>
<td>SML(T) = 0.05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0.05 mg/kg (2) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.</td>
</tr>
<tr>
<td>68125</td>
<td>037244-96-5</td>
<td>Nepheline syenite</td>
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</tr>
<tr>
<td>68145</td>
<td>080410-33-9</td>
<td>2,2′,2″-Nitrilo(triethyl tris(3,3′,5,5′-tetra-tert-buty-1,1′-bi-phenyl-2,2″-diyl)phosphate)</td>
<td>SML =5 mg/kg (sum of phosphate and phosphate)</td>
</tr>
<tr>
<td>68960</td>
<td>000301-02-0</td>
<td>Oleamide</td>
<td></td>
</tr>
<tr>
<td>69040</td>
<td>000112-80-1</td>
<td>Oleic acid</td>
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<tr>
<td>69760</td>
<td>000143-28-2</td>
<td>Oleyl alcohol</td>
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</tr>
<tr>
<td>69920</td>
<td>000144-62-7</td>
<td>Oxalic acid</td>
<td>SML(T) = 6 mg/kg (3)</td>
</tr>
<tr>
<td>70000</td>
<td>070331-94-1</td>
<td>2′,2″-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]</td>
<td></td>
</tr>
<tr>
<td>70240</td>
<td>012198-93-5</td>
<td>Ozokerite</td>
<td></td>
</tr>
<tr>
<td>70400</td>
<td>000057-10-3</td>
<td>Palmitic acid</td>
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<tr>
<td>71020</td>
<td>000373-49-9</td>
<td>Palmitoleic acid</td>
<td></td>
</tr>
<tr>
<td>71440</td>
<td>009000-69-5</td>
<td>Pectin</td>
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</tr>
<tr>
<td>71600</td>
<td>000115-77-5</td>
<td>Pentaerythritol</td>
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<tr>
<td>71635</td>
<td>025151-96-6</td>
<td>Pentaerythritol dioleate</td>
<td>SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.</td>
</tr>
<tr>
<td>71670</td>
<td>178671-58-4</td>
<td>Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)</td>
<td>SML = 0.05 mg/kg</td>
</tr>
<tr>
<td>71680</td>
<td>006683-19-8</td>
<td>Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]</td>
<td></td>
</tr>
<tr>
<td>Ref. No</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td>71720</td>
<td>000109-66-0</td>
<td>Pentane</td>
<td></td>
</tr>
<tr>
<td>72640</td>
<td>007664-38-2</td>
<td>Phosphoric acid</td>
<td></td>
</tr>
<tr>
<td>73160</td>
<td>—</td>
<td>Phosphoric acid, mono- and di- n-alkyl (C_{16} and C_{18}) esters</td>
<td>SML = 0,05 mg/kg</td>
</tr>
<tr>
<td>73720</td>
<td>000115-96-8</td>
<td>Phosphoric acid, trichloroethyl ester</td>
<td>SML = ND (DL = 0,02 mg/kg, analytical tolerance included)</td>
</tr>
<tr>
<td>74010</td>
<td>145650-60-8</td>
<td>Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester</td>
<td>SML = 5 mg/kg (sum of phospite and phosphate)</td>
</tr>
<tr>
<td>74240</td>
<td>031570-04-4</td>
<td>Phosphorous acid, tris(2,4-di-tert-butylphenyl) ester</td>
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<td>74480</td>
<td>000088-99-3</td>
<td>α-Phthalic acid</td>
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<tr>
<td>76320</td>
<td>000085-44-9</td>
<td>Pthalic anhydride</td>
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<tr>
<td>76415</td>
<td>019455-79-9</td>
<td>Pimelic acid, calcium salt</td>
<td></td>
</tr>
<tr>
<td>76721</td>
<td>009016-00-6</td>
<td>Polydimethylsiloxane (Mw &gt; 6800)</td>
<td>In compliance with the specifications laid down in Annex V</td>
</tr>
<tr>
<td></td>
<td>063148-62-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>76730</td>
<td>—</td>
<td>Polydimethylsiloxane, gamma-hydroxypropylated</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>76815</td>
<td>—</td>
<td>Polyesters of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C_{12}-C_{18} fatty acids</td>
<td>In compliance with the specifications laid down in Annex V</td>
</tr>
<tr>
<td>76845</td>
<td>031831-53-5</td>
<td>Polyester of 1,4-butanediol with caprolactone</td>
<td>In compliance with the specifications laid down in Annex V</td>
</tr>
<tr>
<td>76866</td>
<td>—</td>
<td>Polysters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropylene glycol 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</td>
<td>SML = 30 mg/kg</td>
</tr>
<tr>
<td>76960</td>
<td>025322-68-3</td>
<td>Polyethyleneglycol</td>
<td></td>
</tr>
<tr>
<td>77370</td>
<td>070142-34-6</td>
<td>Polyethyleneglycol-30 dipolyhydroxystearate</td>
<td></td>
</tr>
<tr>
<td>77600</td>
<td>061788-85-0</td>
<td>Polyethyleneglycol ester of hydrogenated castor oil</td>
<td></td>
</tr>
<tr>
<td>77702</td>
<td>—</td>
<td>Polyethyleneglycol esters of aliph. monocarb. acids (C_{12}-C_{14}) and their ammonium and sodium sulphates</td>
<td></td>
</tr>
<tr>
<td>77895</td>
<td>068439-49-6</td>
<td>Polyethyleneglycol (EO = 2-6) monoalkyl (C_{18}C_{18}) ether</td>
<td>M2 SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V</td>
</tr>
<tr>
<td>79040</td>
<td>009005-64-5</td>
<td>Polyethyleneglycol sorbitan monolaurate</td>
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</tr>
<tr>
<td>79120</td>
<td>009005-65-6</td>
<td>Polyethyleneglycol sorbitan monooleate</td>
<td></td>
</tr>
<tr>
<td>79200</td>
<td>009005-66-7</td>
<td>Polyethyleneglycol sorbitan monopalmitate</td>
<td></td>
</tr>
<tr>
<td>79280</td>
<td>009005-67-8</td>
<td>Polyethyleneglycol sorbitan monostearate</td>
<td></td>
</tr>
<tr>
<td>79360</td>
<td>009005-70-3</td>
<td>Polyethyleneglycol sorbitan trioleate</td>
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<tr>
<td>79440</td>
<td>009005-71-4</td>
<td>Polyethyleneglycol sorbitan tristearate</td>
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</tr>
<tr>
<td>Ref. No</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
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<td>79600</td>
<td>009046-01-9</td>
<td>Polyethyleneglycol tridecyl ether phosphate</td>
<td>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</td>
</tr>
<tr>
<td>80000</td>
<td>009002-88-4</td>
<td>Polyethylene wax</td>
<td></td>
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<td>80400</td>
<td>029894-35-7</td>
<td>Polyglycerol ricinoleate</td>
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<tr>
<td>80640</td>
<td>—</td>
<td>Polyoxyalkyl (C₂-C₄) dimethylpolysiloxane</td>
<td></td>
</tr>
<tr>
<td>80720</td>
<td>008017-16-1</td>
<td>Polyphosphoric acids</td>
<td></td>
</tr>
<tr>
<td>80800</td>
<td>025322-69-4</td>
<td>Polypropylene glycol</td>
<td></td>
</tr>
<tr>
<td>81060</td>
<td>009003-07-0</td>
<td>Polypropylene wax</td>
<td></td>
</tr>
<tr>
<td>81220</td>
<td>192268-64-7</td>
<td>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'-tetrabutyln-N''-&lt;2,2,6,6-tetramethyl-4-piperidinyl]-N''-&lt;6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N''-tetrabutyln-[1,3,5-triazine-2,4-diamine]</td>
<td>SML = 5 mg/kg</td>
</tr>
<tr>
<td>81515</td>
<td>087189-25-1</td>
<td>Poly(zinc glycerolate)</td>
<td>M3 SML(T) = 25 mg/kg (°) (as Zinc)</td>
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<tr>
<td>81520</td>
<td>007758-02-3</td>
<td>Potassium bromide</td>
<td></td>
</tr>
<tr>
<td>81600</td>
<td>001310-58-3</td>
<td>Potassium hydroxide</td>
<td></td>
</tr>
<tr>
<td>81760</td>
<td>—</td>
<td>Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron</td>
<td>M3 SML(T) = 5 mg/kg (°) (expressed as Copper)</td>
</tr>
<tr>
<td>81840</td>
<td>—</td>
<td>1,2-Propanediol</td>
<td></td>
</tr>
<tr>
<td>81882</td>
<td>—</td>
<td>1,2-Propanol</td>
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<td>82000</td>
<td>—</td>
<td>Propionic acid</td>
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<tr>
<td>82080</td>
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<td>1,2-Propyleneglycol alginate</td>
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<tr>
<td>82240</td>
<td>022788-19-8</td>
<td>1,2-Propyleneglycol dilaurate</td>
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<tr>
<td>82400</td>
<td>000105-62-4</td>
<td>1,2-Propyleneglycol dioleate</td>
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<td>82560</td>
<td>033587-20-1</td>
<td>1,2-Propyleneglycol dipalmitate</td>
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<td>82720</td>
<td>006182-11-2</td>
<td>1,2-Propyleneglycol distearate</td>
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<td>82800</td>
<td>027194-74-7</td>
<td>1,2-Propyleneglycol monolaureate</td>
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<td>82960</td>
<td>001330-80-9</td>
<td>1,2-Propyleneglycol monooleate</td>
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<td>83120</td>
<td>029013-28-3</td>
<td>1,2-Propyleneglycol monopalmitate</td>
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<td>83300</td>
<td>001323-39-3</td>
<td>1,2-Propyleneglycol monostearate</td>
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<td>83320</td>
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<td>Propylhydroxyethylcellulose</td>
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</tr>
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<td>83325</td>
<td>—</td>
<td>Propylhydroxyethylcellulose</td>
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<td>83330</td>
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<td>Propylhydroxypropylcellulose</td>
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<td>83440</td>
<td>002466-09-3</td>
<td>Pyrophosphoric acid</td>
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<td>013445-56-2</td>
<td>Pyrophosphorous acid</td>
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<td>Pyrophylite</td>
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<td>014808-60-7</td>
<td>Quartz</td>
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<tr>
<td>Ref. No</td>
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<td>Restrictions and/or specifications</td>
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<td>83599</td>
<td>068442-12-6</td>
<td>Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin</td>
<td>SML(T) = 0,18 mg/kg (*3) (expressed as Tin)</td>
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<td>83610</td>
<td>073138-82-6</td>
<td>Resin acids and Rosin acids</td>
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<td>83840</td>
<td>008050-09-7</td>
<td>Rosin</td>
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<tr>
<td>84000</td>
<td>008050-31-5</td>
<td>Rosin, ester with glycerol</td>
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<td>84080</td>
<td>008050-26-8</td>
<td>Rosin, ester with pentaerythritol</td>
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<tr>
<td>84210</td>
<td>065997-06-0</td>
<td>Rosin, hydrogenated</td>
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<td>84240</td>
<td>065997-13-9</td>
<td>Rosin, hydrogenated, ester with glycerol</td>
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<td>84320</td>
<td>008050-15-5</td>
<td>Rosin, hydrogenated, ester with methanol</td>
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<td>84400</td>
<td>064365-17-9</td>
<td>Rosin, hydrogenated, ester with pentaerythritol</td>
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<td>84560</td>
<td>009006-04-6</td>
<td>Rubber, natural</td>
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<td>84640</td>
<td>000069-72-7</td>
<td>Salicylic acid</td>
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<td>85360</td>
<td>000109-43-3</td>
<td>Sebacic acid, dibutyl ester</td>
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<td>85601</td>
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<td>Silicates, natural (with the exception of asbestos)</td>
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<tr>
<td>85610</td>
<td></td>
<td>Silicates, natural, silanated (with the exception of asbestos)</td>
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<tr>
<td>85680</td>
<td>001343-98-2</td>
<td>Silicic acid</td>
<td>SML(T) = 0,6 mg/kg (*) (expressed as Lithium)</td>
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<td>85840</td>
<td>053320-86-8</td>
<td>Silicic acid, lithium magnesium sodium salt</td>
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<td>86000</td>
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<td>Silicic acid, silylated</td>
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<td>86160</td>
<td>000409-21-2</td>
<td>Silicon carbide</td>
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<td>86240</td>
<td>007631-86-9</td>
<td>Silicon dioxide</td>
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<td>86285</td>
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<td>Silicon dioxide, silanated</td>
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<td>86560</td>
<td>007647-15-6</td>
<td>Sodium bromide</td>
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<td>001310-73-2</td>
<td>Sodium hydroxide</td>
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<td>Sorbic acid</td>
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<td>Sorbitan monobehenate</td>
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<td>001338-39-2</td>
<td>Sorbitan monolaurate</td>
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<td>87680</td>
<td>001338-43-8</td>
<td>Sorbitan monooleate</td>
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<td>87760</td>
<td>026266-57-9</td>
<td>Sorbitan monopalmitate</td>
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<td>87840</td>
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<td>Sorbitan monostearate</td>
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<td>Sorbitan tetrastearate</td>
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<td>054140-20-4</td>
<td>Sorbitan tripalmitate</td>
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<td>026658-19-5</td>
<td>Sorbitan tristearate</td>
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<td>88320</td>
<td>000050-70-4</td>
<td>Sorbitol</td>
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<td>026836-47-5</td>
<td>Sorbitol monostearate</td>
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<tr>
<td>Ref. No.</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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<tr>
<td>88640</td>
<td>008013-07-8</td>
<td>Soybean oil, epoxidised</td>
<td>▶M3 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 Commission 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.</td>
</tr>
<tr>
<td>88800</td>
<td>009005-25-8</td>
<td>Starch, edible</td>
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<td>88880</td>
<td>068412-29-3</td>
<td>Starch, hydrolysed</td>
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<td>000124-26-5</td>
<td>Stearamide</td>
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<td>89040</td>
<td>000057-11-4</td>
<td>Stearic acid</td>
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</tr>
<tr>
<td>89200</td>
<td>007617-31-4</td>
<td>Stearic acid, copper salt</td>
<td>▶M3 SML(T) = 5 mg/kg (1) (expressed as Copper) ▶</td>
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<td>Stearic acid, esters with ethyleneglycol</td>
<td>SML(T) = 30 mg/kg (1)</td>
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<td>Stearylbenzylmethane</td>
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<td>Stearoyl-2-lactylic acid, calcium salt</td>
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<td>Succinic acid</td>
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<td>Sucrose acetate isobutyrate</td>
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<td>Sucrose octaacetate</td>
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<td>010124-44-4</td>
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<td>Tartaric acid</td>
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<td>Taurine, salts</td>
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<td>Terephthalic acid, diester with 2,2'-methylene-nebis(4-methyl-6-tert-butylphenol)</td>
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<td>N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine</td>
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<td>078301-43-6</td>
<td>2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.1.12]-heneicosan-21-one, polymer</td>
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<td>92930</td>
<td>120218-34-0</td>
<td>Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)</td>
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<td>SML = 6 mg/kg</td>
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<td>Restrictions and/or specifications</td>
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<td>Trimethylolpropane trimethacrylate-methyl methacrylate copolymer</td>
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<td>1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene</td>
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<td>95270</td>
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<td>2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphate</td>
<td>SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)</td>
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<td>95725</td>
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<td>Vermiculite, reaction product with citric acid, lithium salt</td>
<td>SML(T) = 0.6 mg/kg (*) (expressed as Lithium)</td>
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<td>95855</td>
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<td>Water</td>
<td>In compliance with Directive 98/83/EEC</td>
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<td>Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks</td>
<td>In compliance with the specifications laid down in Annex V</td>
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<td>White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks</td>
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<td>Wood flour and fibers, untreated</td>
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<td>95935</td>
<td>011138-66-2</td>
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<td>96190</td>
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<td>Zinc hydroxide</td>
<td>►M3 SML(T) = 25 mg/kg ((^*)) (as Zinc) ◄</td>
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<td>96240</td>
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<td>Zinc oxide</td>
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<td>Zinc sulphide</td>
<td>►M3 SML(T) = 25 mg/kg ((^*)) (as Zinc) ◄</td>
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### Incomplete list of additives referred to in Article 4, second paragraph

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<td>30180</td>
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<td>SML(T) = 0.6 mg/kg (expressed as Manganese)</td>
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<td>31500</td>
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<td>Acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer</td>
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<td>Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester</td>
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<td>SML = 18 mg/kg</td>
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<td>34230</td>
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<td>Antimony trioxide</td>
<td>SML = 0.02 mg/kg (expressed as Antimony and analytical tolerance included)</td>
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<td>Aluminium hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl)] phosphate</td>
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<td>Barium nitrate</td>
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<td>2,5-Bis(5-tert-butyl-2-benzoxazolyl) thiophene</td>
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<td>032687-78-8</td>
<td>N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)proponionyl)hydrazide</td>
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<td>38820</td>
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<td>Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphate</td>
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<td>2,4-Bis(dodecythiomethyl)-6-methylphenol</td>
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<td>N,N-Bis(2-hydroxyethyl)alkyl(C11-C18)amine</td>
<td>SML(T) = 1.2 mg/kg (expressed as Tertiary amine) (expressed excluding HCl)</td>
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<td>N,N-Bis(2-hydroxyethyl)alkyl(C11-C18)amine hydrochlorides</td>
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<td>2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylamino)-1,3,5-triazine</td>
<td>SML = 30 mg/kg</td>
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<td>110553-27-0</td>
<td>2,4-Bis(octylthiomethyl)-6-methylphenol</td>
<td>▼M3 SML(T) = 5 mg/kg (expressed as Tertiary amine) (expressed excluding HCl)</td>
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<td>N,N’-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer</td>
<td>SML = 2,4 mg/kg</td>
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<td>tert-Butyl-4-hydroxyanisole (= BHA)</td>
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<td>013003-12-8</td>
<td>4,4’-Butylidene-bis(6-tert-butyl-3-methyl-phenyl-ditridecyl phosphate)</td>
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<td>40980</td>
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<td>Butyric acid, manganese salt</td>
<td>SML(T) = 0,6 mg/kg (“) (expressed as Manganese)</td>
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<td>42000</td>
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<td>(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)</td>
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<td>1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride</td>
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<td>Cobalt oxide</td>
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<td>Cresols, butylated, styrenated</td>
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<td>2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester</td>
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<td>2,6-Di-tert-butyl-p-cresol (= BHT)</td>
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<td>Di-n-dodecytin bis(isooctyl mercaptoacetate)</td>
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<td>Dioctadecyl disulphide</td>
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<td>50160</td>
<td>—</td>
<td>Di-octyltin bis(n-alkyl(C10-C16) mercaptoacetate)</td>
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<td>Di-n-octyltin bis(2-ethylhexyl maleate)</td>
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<td>Di-n-octyltin dimaleate</td>
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<td>Di-n-octyltin dimaleate, esterified</td>
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<td>Di-n-octyltin dimaleate, polymers (n = 2-4)</td>
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<td>Di-n-octyltin ethyleneglycol bis(mercaptaoacetate)</td>
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<td>Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptaacetate</td>
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<td>51570</td>
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<td>Diphenyl sulphone</td>
<td>SML(T) = 3 mg/kg (i)</td>
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<td>Dodecylbenzenesulphonic acid</td>
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<td>2-(4-Dodecylphenyl)indole</td>
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<td>4-Ethoxybenzoic acid, ethyl ester</td>
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<td>2-Ethoxy-2'-ethyloxanilide</td>
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<td>001166-52-5</td>
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<td>000121-79-9</td>
<td>Gallic acid, propyl ester</td>
<td>SML(T) = 30 mg/kg (i)</td>
</tr>
</tbody>
</table>

**C1**

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<tr>
<th>Ref. No</th>
<th>CAS No</th>
<th>Name</th>
<th>Restrictions and/or specifications</th>
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<tr>
<td>58960</td>
<td>000057-09-0</td>
<td>Hexadeccyltrimethylammonium bromide</td>
<td>SML = 6 mg/kg</td>
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<tr>
<td>59120</td>
<td>023128-74-7</td>
<td>1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)</td>
<td>SML = 45 mg/kg</td>
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<td>59200</td>
<td>035074-77-2</td>
<td>1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)</td>
<td>SML = 6 mg/kg</td>
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<tr>
<td>60320</td>
<td>070321-86-7</td>
<td>2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole</td>
<td>SML = 1,5 mg/kg</td>
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<tr>
<td>60400</td>
<td>003896-11-5</td>
<td>2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole</td>
<td>SML(T) = 30 mg/kg (i)</td>
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<td>60800</td>
<td>065447-77-0</td>
<td>1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer</td>
<td>SML = 30 mg/kg</td>
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<td>61280</td>
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<td>2-Hydroxy-4-n-hexyloxybenzophenone</td>
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<td>2-Hydroxy-4-methoxybenzophenone</td>
<td>SML(T) = 6 mg/kg (i)</td>
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<td>2-(2'-Hydroxy-5'-methylphenyl)benzotriazole</td>
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<td>2-Hydroxy-4-n-octyloxybenzophenone</td>
<td>SML(T) = 6 mg/kg (i)</td>
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<td>051877-53-3</td>
<td>Lactic acid, manganese salt</td>
<td>SML(T) = 0,6 mg/kg (i) (expressed as Manganese)</td>
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<td>CAS No</td>
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<td>Restrictions and/or specifications</td>
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<td>▼C1</td>
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<td>▼M3</td>
<td>63940</td>
<td>008062-15-5</td>
<td>Lignosulphonic acid</td>
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<td>▼C1</td>
<td>64320</td>
<td>010377-51-2</td>
<td>Lithium iodide</td>
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<td>007773-01-5</td>
<td>Manganese chloride</td>
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<td>▼C1</td>
<td>65200</td>
<td>012626-88-9</td>
<td>Manganese hydroxide</td>
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<td>65280</td>
<td>010043-84-2</td>
<td>Manganese hypophosphate</td>
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<td>011129-60-5</td>
<td>Manganese oxide</td>
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<td>66350</td>
<td>085209-93-4</td>
<td>2,2’-Methylenebis(4,6-di-tert-butylphenyl) lithium phosphate</td>
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<td>000088-24-4</td>
<td>2,2’-Methylene bis(4-ethyl-6-tert-butylphenol)</td>
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<td>67515</td>
<td>057583-34-3</td>
<td>Monomethyltin tris(ethylhexyl mercaptoacetate)</td>
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<td>Monomethyltin tris(isooctyl mercaptoacetate)</td>
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<td>Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)</td>
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<td>▼M2</td>
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<td>Mono-n-octyltin tris(isooctyl mercaptoacetate)</td>
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<td>Myristic acid, lithium salt</td>
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<td>Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate</td>
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<td>004724-48-5</td>
<td>n-Octylphosphonic acid</td>
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<td>CAS No</td>
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<td>▼M3</td>
<td>69160</td>
<td>014666-94-5 Oleic acid, cobalt salt</td>
<td>SML(T) = 0.05 mg/kg ((^{14})) (expressed as Cobalt)</td>
</tr>
<tr>
<td>▼C1</td>
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<td>016260-09-6 Oleyl palmitamide</td>
<td>SML = 5 mg/kg</td>
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<td>▼M2</td>
<td>71935</td>
<td>007601-89-0 Perchloric acid, sodium salt monohydrate</td>
<td>SML = 0.05 mg/kg ((^{19}))</td>
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<td>▼C1</td>
<td>72160</td>
<td>000948-65-2 2-Phenylindole</td>
<td>SML = 15 mg/kg</td>
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<td></td>
<td>72800</td>
<td>001241-94-7 Phosphoric acid, diphenyl 2-ethylhexyl ester</td>
<td>SML = 2,4 mg/kg</td>
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<td>73040</td>
<td>013763-32-1 Phosphoric acid, lithium salts</td>
<td>SML(T) = 0.6 mg/kg ((^{1})) (expressed as Lithium)</td>
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<td>73120</td>
<td>010124-54-6 Phosphoric acid, manganese salt</td>
<td>SML(T) = 0.6 mg/kg ((^{10})) (expressed as Manganese)</td>
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<td>74400</td>
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<td>SML = 30 mg/kg</td>
</tr>
<tr>
<td>▼M3</td>
<td>76681</td>
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<td>SML = 5 mg/kg ((^{1}))</td>
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<td>▼C1</td>
<td>77440</td>
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<td>77520</td>
<td>061791-12-6 Polyethylene glycol ester of castor oil</td>
<td>SML = 42 mg/kg</td>
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<td>78320</td>
<td>0009004-97-1 Polyethylene glycol monoricinoleate</td>
<td>SML = 42 mg/kg</td>
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<td>81200</td>
<td>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]</td>
<td>SML = 3 mg/kg</td>
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<tr>
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<td>81680</td>
<td>007681-11-0 Potassium iodide</td>
<td>SML(T) = 1 mg/kg ((^{15})) (expressed as Iodium)</td>
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<td>019019-51-3 Propionic acid, cobalt salt</td>
<td>SML(T) = 0.05 mg/kg ((^{14})) (expressed as Cobalt)</td>
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<tr>
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<td>83595</td>
<td>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</td>
<td>SML = 18 mg/kg and in compliance with the specifications mentioned in Annex V.</td>
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<td>83700</td>
<td>000141-22-0 Ricinoleic acid</td>
<td>SML = 42 mg/kg</td>
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<td>84800</td>
<td>000087-18-3 Salicylic acid, 4-tert-butylphenyl ester</td>
<td>SML = 12 mg/kg</td>
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<td>84880</td>
<td>000119-36-8 Salicylic acid, methyl ester</td>
<td>SML = 30 mg/kg</td>
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<td>85760</td>
<td>012068-40-5 Silicic acid, lithium aluminium salt(2:1:1)</td>
<td>SML(T) = 0.6 mg/kg ((^{1})) (expressed as Lithium)</td>
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<td>85920</td>
<td>012627-14-4 Silicic acid, lithium salt</td>
<td>SML(T) = 0.6 mg/kg ((^{1})) (expressed as Lithium)</td>
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<td>▼M3</td>
<td>85950</td>
<td>037296-97-2 Silicic acid, magnesium-sodium-fluoride salt</td>
<td>SML = 0.15 mg/kg (expressed as fluoride). Only to be used in layers of multilayers materials not coming into direct contact with food</td>
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<tr>
<td>▼M2</td>
<td>86480</td>
<td>007631-90-5 Sodium bisulphite</td>
<td>SML(T) = 10 mg/kg ((^{16})) (expressed as S0)</td>
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<tr>
<td>▼C1</td>
<td>86800</td>
<td>007681-82-5 Sodium iodide</td>
<td>SML(T) = 1 mg/kg ((^{15})) (expressed as Iodine)</td>
</tr>
<tr>
<td>Ref. No</td>
<td>CAS No</td>
<td>Name</td>
<td>Restrictions and/or specifications</td>
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</tr>
<tr>
<td>86880</td>
<td>—</td>
<td>Sodium monoalkyl dialkylphenoxybenzene-disulphonate</td>
<td>SML = 9 mg/kg</td>
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<tr>
<td>86920</td>
<td>007632-00-0</td>
<td>Sodium nitrite</td>
<td>SML = 0.6 mg/kg</td>
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<tr>
<td>86960</td>
<td>007757-83-7</td>
<td>Sodium sulphite</td>
<td>SML(T) = 10 mg/kg (?) (expressed as S0₂)</td>
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<td>87120</td>
<td>007772-98-7</td>
<td>Sodium thiosulphate</td>
<td>SML(T) = 10 mg/kg (?) (expressed as S0₂)</td>
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<td>89170</td>
<td>013586-84-0</td>
<td>Stearic acid, cobalt salt</td>
<td>SML(T) = 0.05 mg/kg (?) (expressed as Cobalt)</td>
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<td>92000</td>
<td>007727-43-7</td>
<td>Sulphuric acid, barium salt</td>
<td>SML(T) = 1 mg/kg (?) (expressed as Barium)</td>
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<tr>
<td>92320</td>
<td>—</td>
<td>Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid</td>
<td>SML = 15 mg/kg</td>
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<tr>
<td>92560</td>
<td>038613-77-3</td>
<td>Tetrakis(2,4-di-tert-butyl-phenyl)-4,4’-biphenylidinephosphonite</td>
<td>SML = 18 mg/kg</td>
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<td>92800</td>
<td>000096-69-5</td>
<td>4,4’-Thiobis(6-terc-butyl-3-methylphenol)</td>
<td>SML = 0.48 mg/kg</td>
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<td>92880</td>
<td>041484-35-9</td>
<td>Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)</td>
<td>SML = 2.4 mg/kg</td>
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<td>93120</td>
<td>000123-28-4</td>
<td>Thioldipropionic acid, didodecyl ester</td>
<td>SML(T) = 5 mg/kg (?)</td>
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<td>93280</td>
<td>000693-36-7</td>
<td>Thioldipropionic acid, dioctadecyl ester</td>
<td>SML(T) = 5 mg/kg (?)</td>
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<td>94400</td>
<td>036443-68-2</td>
<td>Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]</td>
<td>SML = 9 mg/kg</td>
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<td>94560</td>
<td>000122-20-3</td>
<td>Triisopropanolamine</td>
<td>SML = 5 mg/kg</td>
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<td>95265</td>
<td>227099-60-7</td>
<td>1,3,5-Tris(4-benzoylphenyl) benzene</td>
<td>SML = 0.05 mg/kg</td>
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<td>95280</td>
<td>040601-76-1</td>
<td>1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione</td>
<td>SML = 6 mg/kg</td>
</tr>
<tr>
<td>95360</td>
<td>027676-62-6</td>
<td>1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione</td>
<td>SML = 5 mg/kg</td>
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<tr>
<td>95600</td>
<td>001843-03-4</td>
<td>1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane</td>
<td>SML = 5 mg/kg</td>
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### ANNEX IV

**PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION**

<table>
<thead>
<tr>
<th>Reference No</th>
<th>CAS No</th>
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<td>(4)</td>
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<tr>
<td>18888</td>
<td>080181-31-3</td>
<td>3-Hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer</td>
<td>In compliance with specifications included in Annex V</td>
</tr>
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</table>
Annex V

Specifications

Part A: General specifications

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0.02 mg/kg of food or food simulant, analytical tolerance included). However, the migration value of the primary aromatic amines listed in this Directive are excluded from this restriction.

Part B: Other specifications

Ref. No | OTHER SPECIFICATIONS
---|---
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 H16 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**

```
   CH3
   |
CH3 O CH2 O
   |
```

\[(O-CH-CH2-C)n \cdot (O-CH-CH2-C)\]

where n/(m + n) greater than 0 and less than 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-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids

**Description** White to off-white powder after isolation
### OTHER SPECIFICATIONS

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<td>Identification tests:</td>
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<td></td>
<td>Solubility Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water</td>
</tr>
<tr>
<td></td>
<td>Restriction QMA for crotonic acid is 0.05 mg/6 dm²</td>
</tr>
<tr>
<td></td>
<td>Purity Prior to granulation the raw material copolymer powder must contain:</td>
</tr>
<tr>
<td></td>
<td>— nitrogen Not more than 2 500 mg/kg of plastic</td>
</tr>
<tr>
<td></td>
<td>— zinc Not more than 100 mg/kg of plastic</td>
</tr>
<tr>
<td></td>
<td>— copper Not more than 5 mg/kg of plastic</td>
</tr>
<tr>
<td></td>
<td>— lead Not more than 2 mg/kg of plastic</td>
</tr>
<tr>
<td></td>
<td>— arsenic Not more than 1 mg/kg of plastic</td>
</tr>
<tr>
<td></td>
<td>— chromium Not more than 1 mg/kg of plastic</td>
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</tbody>
</table>

### ▼M2

#### 23547 Polydimethylsiloxane (Mw > 6 800)

Minimum viscosity $100 \times 10^{-6} \text{m}^2/\text{s} (= 100 \text{centistokes})$ at 25 °C

### ▼C1

#### 24903 Syrups, hydrolysed starch, hydrogenated


### ▼M3

#### 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)

### ▼C1

#### 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, 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)

### ▼M3

#### 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)
<table>
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<td>▼M3 64990</td>
<td>Maleic anhydride-styrene, copolymer, sodium salt</td>
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<td>MW fraction &lt; 1 000 is less than 0,05 % (w/w)</td>
</tr>
<tr>
<td>▼M3 67155</td>
<td>Mixture of 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxa-</td>
</tr>
<tr>
<td></td>
<td>zolyl) stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene</td>
</tr>
<tr>
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<td>Mixture obtained from the manufacturing process in the typical ratio of (58-62 %):(23-</td>
</tr>
<tr>
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<td>27 %): (13-17 %)</td>
</tr>
<tr>
<td>▼C1 76721</td>
<td>Polydimethylsiloxane (Mw &gt; 6 800)</td>
</tr>
<tr>
<td></td>
<td>Minimum viscosity $100 \times 10^{-6}$ m²/s (= 100 centistokes) at 25 °C</td>
</tr>
<tr>
<td>▼M3 76845</td>
<td>Polyester of 1,4-butanediol with caprolactone</td>
</tr>
<tr>
<td></td>
<td>MW fraction &lt; 1 000 is less than 0,05 % (w/w)</td>
</tr>
<tr>
<td>▼M3 76815</td>
<td>Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered,</td>
</tr>
<tr>
<td></td>
<td>unbranched C12-C22 fatty acids</td>
</tr>
<tr>
<td></td>
<td>MW fraction &lt; 1 000 is less than 5 % (w/w)</td>
</tr>
<tr>
<td>▼M2 77895</td>
<td>Polyethyleneglycol (EO = 2-6) monoalkyl (C₁₆-C₁₈) ether</td>
</tr>
<tr>
<td></td>
<td>The composition of this mixture is as follows:</td>
</tr>
<tr>
<td></td>
<td>— polyethyleneglycol (EO = 2-6)monoalkyl (C₁₆-C₁₈) ether (approximately 28 %)</td>
</tr>
<tr>
<td></td>
<td>— fatty alcohols (C₁₆-C₁₈) (approximately 48 %)</td>
</tr>
<tr>
<td></td>
<td>— ethyleneglycol monoalkyl (C₁₆-C₁₈) ether (approximately 24 %)</td>
</tr>
<tr>
<td>▼M3 79600</td>
<td>Polyethyleneglycol tridecyl ether phosphate</td>
</tr>
<tr>
<td></td>
<td>Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono-and dialkyl ester) with a</td>
</tr>
<tr>
<td></td>
<td>maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether</td>
</tr>
<tr>
<td>▼C1 83595</td>
<td>Reaction product of di-tert-butylphosphonite with biphienyl, obtained by condensation of</td>
</tr>
<tr>
<td></td>
<td>2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and</td>
</tr>
<tr>
<td></td>
<td>biphienyl</td>
</tr>
<tr>
<td></td>
<td>Composition:</td>
</tr>
<tr>
<td></td>
<td>— 4,4'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 38613-77-</td>
</tr>
<tr>
<td></td>
<td>3) (36-46 % w/w (*)),</td>
</tr>
<tr>
<td></td>
<td>— 4,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 118421-00-</td>
</tr>
<tr>
<td></td>
<td>4 (17-23 % w/w (*)),</td>
</tr>
<tr>
<td></td>
<td>— 3,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 118421-01-</td>
</tr>
<tr>
<td></td>
<td>5) (1-5 % w/w (*)),</td>
</tr>
<tr>
<td></td>
<td>— 4-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate (CAS.No 91362-37-7) (11-</td>
</tr>
<tr>
<td></td>
<td>19 % w/w (*)),</td>
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<tr>
<td></td>
<td>— Tris(2,4-di-tert-butylphenyl)phosphite (CAS.No 31570-04-4) (9-18 % w/w (*)),</td>
</tr>
<tr>
<td></td>
<td>— 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-</td>
</tr>
<tr>
<td></td>
<td>butylphenyl)phosphonite (CAS.No 112949-97-0) (&lt; 5 % w/w (*)).</td>
</tr>
<tr>
<td></td>
<td>Other specifications:</td>
</tr>
<tr>
<td></td>
<td>— Phosphor content of min. 5,4 % to max. 5,9 %</td>
</tr>
<tr>
<td></td>
<td>— Acid value of max. 10 mg KOH per gram</td>
</tr>
<tr>
<td></td>
<td>— Melt range of 85-110 °C</td>
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### OTHER SPECIFICATIONS

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<tr>
<th>Ref. No</th>
<th>Description</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>88640</td>
<td>Soybean oil, epoxidized</td>
<td>Oxirane &lt; 8 %, iodine number &lt; 6</td>
</tr>
</tbody>
</table>
| 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 $11 \times 10^{-6}$ m²/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 $8,5 \times 10^{-6}$ m²/s (= 8,5 centistokes) at 100 °C  
- Average molecular weight not less than 480 |

(*) Quantity of substance used / quantity of formulation
ANNEX VI

NOTES RELATED TO THE COLUMN ‘RESTRICTIONS AND/OR SPECIFICATIONS’

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

(2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as 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) 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.

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

(9) 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: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.

(10) 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.

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

(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: 39090 and 39120.

(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 44960, 68078, 69160, 82020 and 89170.

(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 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(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 49595, 49600, 67520, 67515 and 83599.

(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: 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.

(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.

(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 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.
ANNEX VII

Part A

REPEALED DIRECTIVE AND ITS AMENDMENTS

(Referred to by Article 10(1))


Part B

DEADLINES FOR TRANSPPOSITION INTO NATIONAL LAW

(Referred to by Article 10(1))

<table>
<thead>
<tr>
<th>Directive</th>
<th>Deadlines for transposition</th>
<th>To permit trade in those products which comply with this Directive</th>
<th>To prohibit trade in those products which do not comply with this Directive</th>
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<tbody>
<tr>
<td>95/3/EC (OJ L 41, 23.2.1995, p. 44)</td>
<td>1 April 1996</td>
<td>1 April 1996</td>
<td>1 April 1998</td>
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## ANNEX VIII

### CORRELATION TABLE

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