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► C1 COMMISSION DIRECTIVE

of 23 February 1990

relating to plastics materials and articles intended to come into contact with foodstuffs

(90/128/EEC) ◀

(OJ L 75, 21.3.1990, p. 19)

Amended by:

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► <u>M1</u> Commission Directive 92/39/EEC of 14 May 1992	L 168	21	23.6.1992
► <u>M2</u> Commission Directive 93/9/EEC of 15 March 1993	L 90	26	14.4.1993
► <u>M3</u> Commission Directive 95/3/EC of 14 February 1995	L 41	44	23.2.1995
► <u>M4</u> Commission Directive 96/11/EC of 5 March 1996	L 61	26	12.3.1996
► <u>M5</u> Commission Directive 1999/91/EC of 23 November 1999	L 310	41	4.12.1999

Corrected by:

- C1 Corrigendum, OJ L 349, 13.12.1990, p. 26 (90/128/EEC)
- C2 Corrigendum, OJ L 249, 4.10.2000, p. 26 (1999/91/EC)

▼C1

COMMISSION DIRECTIVE**of 23 February 1990****relating to plastics materials and articles intended to come into contact with foodstuffs**

(90/128/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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,

Whereas 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;

Whereas, in order to achieve this objective in the case of plastics 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;

Whereas the scope of this Directive must coincide with that of Council Directive 82/711/EEC⁽²⁾;

Whereas 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;

Whereas 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;

Whereas the stage reached in the work at Community level does not yet permit adoption of a complete list of the authorized substances applicable to all types of plastics materials and articles and therefore the substances which are currently used in at least one Member State can continue to be used pending a decision on inclusion in the Community list; whereas this Directive will accordingly be extended in due course to the substances and sectors provisionally excluded;

Whereas 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;

Whereas Directive 82/711/EEC lays down the basic rules necessary for testing migration of the constituents of plastics materials and articles and Council Directive 85/572/EEC⁽³⁾ establishes the list of simulants to be used in the migration tests;

⁽¹⁾ OJ No L 40, 11. 2. 1989, p. 38.

⁽²⁾ OJ No L 297, 23. 10. 1982, p. 26.

⁽³⁾ OJ No L 372, 31. 12. 1985, p. 14.

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Whereas Council Directive 78/142/EEC⁽¹⁾ lays down limits for the quantity of vinyl chloride present in plastics materials and articles prepared with this substance and for the quantity of vinyl chloride released by these materials and articles, and Commission Directives 80/766/EEC⁽²⁾ and 81/432/EEC⁽³⁾ establish the Community methods of analysis for controlling these limits;

Whereas Commission Directive 80/590/EEC⁽⁴⁾ determines the symbol that may accompany any material and article intended to come into contact with foodstuffs;

Whereas 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 plastics materials and articles which are not by their nature clearly intended for food use;

Whereas, in accordance with Article 3 of Directive 89/109/EEC, the Scientific Committee for Food has been consulted on the provisions liable to affect public health;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

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 plastics 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 polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.

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

- (i) varnished or unvarnished regenerated cellulose film, covered by Council Directive 83/229/EEC⁽⁵⁾, as amended by Directive 86/388/EEC⁽⁶⁾;
- (ii) elastomers and natural and synthetic rubber;
- (iii) paper and paperboard, whether modified or not by the addition of plastics;
- (iv) 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;

⁽¹⁾ OJ No L 44, 15. 2. 1978, p. 15.

⁽²⁾ OJ No L 213, 16. 8. 1980, p. 42.

⁽³⁾ OJ No L 167, 24. 6. 1981, p. 6.

⁽⁴⁾ OJ No L 151, 19. 6. 1980, p. 21.

⁽⁵⁾ OJ No L 123, 11. 5. 1983, p. 31.

⁽⁶⁾ OJ No L 228, 14. 8. 1986, p. 32.

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(v) ion-exchange resins.

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

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

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

Article 3

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

2. From the date of notification of this Directive, 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.

3. From the date of notification of this Directive no Member State shall authorize any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

▼ M4

4. As from 1 January 2002, only those monomers and other starting substances listed in Annex II, Section A, shall be used for the manufacture of plastic materials and articles, subject to the restrictions specified therein. However, the substances listed in Annex II, Section B, may be deleted before the abovementioned date if the data requested for inclusion in Section A are not supplied in time to permit their evaluation by the Scientific Committee for Food.

▼ C1

5. However 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 polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
- silicones,
- epoxy resins,

▼ M5**▼ C1**

- adhesives and adhesion promoters,
- printing inks.

▼M5*Article 3a*

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

Article 3b

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

Article 3c

1. The specifications relating to some substances appearing in Annexes II, III and IV are laid down in Annex V.
2. The meaning of the numbers between brackets appearing in the Column 'Restrictions and/or specifications' is explained in Annex VI.

▼C1*Article 4*

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

- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
- (b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuff in contact therewith.

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

Article 5

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC and the further provisions set out in Annex I.
2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

▼M2

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.

▼C1*Article 6*

1. At the marketing stages other than the retail stages, the plastics materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC.
2. Paragraph 1 does not apply to plastics materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

Article 7

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1990. They shall forthwith inform the Commission thereof.

▼C1

2. Member States shall:

- permit the trade in and use of plastics materials and articles complying with this Directive before 1 January 1991,
- prohibit trade in and use of plastics materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive as from 1 January 1993.

Article 8

This Directive is addressed to the Member States.

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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:

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

Where:

M is the migration in mg/kg;

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

a₁ is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test;

a₂ is the surface area in dm² of the material or article in real conditions of use;

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

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

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

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

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

4. In accordance with the provisions set out in Article 5 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

▼C1

released by the sample may be carried out by evaporation of the simulant and weighing of the residue.

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

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

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

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M_1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M_2 and M_3 , respectively).

The material or article shall be deemed to be in compliance provided that either M_1 or $M_3 - M_2$ do not exceed the overall migration limit.

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

The following analytical tolerances have been observed:

- 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,
- 6 mg/kg or 1 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 migration determined shall not exceed the overall migration limit.

▼ C1

ANNEX II

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

General introduction

1. This Annex contains the list of monomers or other starting substances. The list includes:
 - substances undergoing polymerization, 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 synthesize them are not included in the list,
 - substances used to modify existing natural or synthetic macromolecular substances.
2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorized acids, phenols or alcohols which are also authorized. However, names containing ‘... acid(s), salts’ appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases, the meaning of the term ‘salts’ is ‘salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc’.
3. The list 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 synthesize them are included in the list;
 - (c) mixtures of the authorized substances.

The materials and articles which contain the substance indicated under (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 ► M3 as regards the purity criteria ◀.
5. The list contains the following information:
 - column 1 (PM/REF. No): the EEC packaging material references number of the substance on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) Registry number,
 - column 3 (Name): the chemical name,

▼ M5

- Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer.

▼ C1

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.

▼ C1

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;

▼ M1

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.

▼ C1

- QM = maximum permitted quantity of the 'residual' substance in the material or article;
 QM (T) = maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated.

▼ M2

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

▼ C1

- SML = specific migration limit in food or in food simulant, unless it is specified otherwise.

▼ M1

For the purpose of this Directive 'SML' means that the specific migration of the substance should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

▼ C1

- SML (T) = specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated.

▼ M2

For the purpose of this Directive 'SML (T)' means that the specific migration of the substances should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

▼ C1

SECTION A

LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	► <u>M5</u> SML(T) = 6 mg/kg (2) ◀
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
▼ <u>M1</u>			
10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg)
▼ <u>M3</u>			
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
▼ <u>C1</u>			
10690	000079-10-7	Acrylic acid	
▼ <u>M2</u>			
10750	002495-35-4	Acrylic acid, benzyl ester	
▼ <u>C1</u>			
10780	000141-32-2	Acrylic acid n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid tert-butyl ester	
▼ <u>M5</u>			
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	QMA = 0,05 mg/6 dm ²
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg (1)
▼ <u>C1</u>			
11470	000140-88-5	Acrylic acid ethyl ester	
	000818-61-1	Acrylic acid hydroxyethyl ester	See 'Acrylic acid, monoester with ethyleneglycol'
11590	00106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
▼ <u>M2</u>			
11890	002499-59-4	Acrylic acid, n-octyl ester	
▼ <u>C1</u>			
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
12130	000124-04-9	Adipic acid	
▼ <u>M5</u>			
12265	004074-90-2	Adipic acid, divinyl ester	QM = 5 mg/kg in FP. For use only as comonomer
▼ <u>M1</u>			
12280	002035-75-8	Adipic anhydride	
▼ <u>C1</u>			
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols aliphatic, monohydric, saturated, linear, primary (C4-C22)	

▼ C1

	PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
	(1)	(2)	(3)	(4)
▼ <u>M1</u>	12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6 mg/kg
▼ <u>M5</u>	12761	000693-57-2	12-Aminododecanoic acid	SML = 0,05 mg/kg
▼ <u>M1</u>	12788	002432-99-7	11-Aminoundecanoic acid	► <u>M2</u> SML = 5 mg/kg ◀
▼ <u>M3</u>	12789	007664-41-7	Ammonia	
▼ <u>C1</u>	12820	000123-99-9	Azelaic acid	
▼ <u>M1</u>	12970	004196-95-6	Azelaic anhydride	
▼ <u>C1</u>	13000	001477-55-0	1,3-Benzenedimethanamine	SML = 0,05 mg/kg
▼ <u>M5</u>	13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	QMA = 0,05 mg/6 dm ² (measured as 1,3,5-benzenetricarboxylic acid)
▼ <u>C1</u>	13090	000065-85-0	Benzoic acid	
	13150	000100-51-6	Benzyl alcohol	
		000111-46-6	Bis(2-hydroxyethyl) ether	See 'Diethyleneglycol'
		000077-99-6	2,2-Bis(hydroxymethyl)-1-butanol	See '1,1,1-Trimethylolpropane'
▼ <u>M5</u>	13180	000498-66-8	Bicyclo[2.2.1]hept-2-ene (= norbornene)	SML = 0,05 mg/kg
	13210	001761-71-3	Bis(4-aminocyclohexyl)-methane	SML = 0,05 mg/kg
▼ <u>C1</u>	13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
	13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 3 mg/kg
	13510	001675-54-3	2,2 Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	► <u>M5</u> SML(T) = 1 mg/kg (9) Authorised until 1 January 2005 ◀
		000110-98-5	Bis(hydroxypropyl) ether	See 'Dipropylenglycol'
		005124-30-1	Bis(4-isocyanatocyclohexyl)-methane	See 'Dicyclohexylmethane-4,4'-diisocyanate'
▼ <u>M1</u>	13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	SML = 0,05 mg/kg
▼ <u>C1</u>	13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)-2-indolinone	SML = 1,8 mg/kg
		000080-05-7	Bisphenol A	See '2,2-Bis(4-hydroxyphenyl)propane'
		001675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See '2,2-Bis(4-hydroxyphenyl)propane-bis(2,3-epoxypropyl) ether'
▼ <u>M1</u>	13614	038103-06-9	Bisphenol A bis(phthalic anhydride)	See 13530

▼ M1

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
▼ <u>C1</u>	13630	000106-99-0	Butadiene	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
	13690	000107-88-0	1,3-Butanediol	
▼ <u>M5</u>	13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43)
▼ <u>C1</u>	13840	000071-36-3	1-Butanol	
	13870	000106-98-9	1-Butene	
	13900	000107-01-7	2-Butene	
▼ <u>M5</u>	14020	000098-54-4	4-tert-Butylphenol	SML = 0,05 mg/kg
▼ <u>C1</u>	14110	000123-72-8	Butyraldehyde	
	14140	000107-92-6	Butyric acid	
	14170	000106-31-0	Butyric anhydride	
	14200	000105-60-2	Caprolactam	► <u>M5</u> SML(T) = 15 mg/kg (5) ◀
	14230	002123-24-2	Caprolactam, sodium salt	► <u>M5</u> SML(T) = 15 mg/kg (5) (expressed as caprolactam) ◀
	14320	000124-07-2	Caprylic acid	
	14350	000630-08-0	Carbon monoxide	
	14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
▼ <u>M3</u>	14411	008001-79-4	Castor oil	
▼ <u>C1</u>	14500	009004-34-6	Cellulose	
	14530	007782-50-5	Chlorine	
		000106-89-8	1-Chloro-2,3-epoxypropane	See 'Epichlorhydrin'
▼ <u>M5</u>	14650	000079-38-9	Chlorotrifluoroethylene	QMA = 0,05 mg/6 dm ²
▼ <u>C1</u>	14680	000077-92-9	Citric acid	
	14710	000108-39-4	<i>m</i> -Cresol	
	14740	000095-48-7	<i>o</i> -Cresol	
	14770	00106-44-5	<i>p</i> -Cresol	
		000105-08-8	1,4-Cyclohexanedimethanol	See '1,4-Bis(hydroxymethyl)cyclohexane'
▼ <u>M5</u>	14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
▼ <u>C1</u>	14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
▼ <u>M3</u>	15070	001647-16-1	1,9-Decadiene	SML = 0,05 mg/kg
▼ <u>M2</u>	15095	000334-48-5	Decanoic acid	
▼ <u>C1</u>	15100	000112-30-1	1-Decanol	
		000107-15-3	1,2-Diaminoethane	See 'Ethylenediamine'
		000124-09-4	1,6-Diaminohexane	See 'Hexamethylenediamine'

▼ C1

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
▼ <u>M5</u>	15130	000872-05-9	1-Decene	SML = 0,05 mg/kg
▼ <u>M1</u>	15250	000110-60-1	1,4-Diaminobutane	
▼ <u>M2</u>	15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
▼ <u>C1</u>	15700	005124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	15760	000111-46-6	Diethyleneglycol	► <u>M5</u> SML(T) = 30 mg/kg (3) ◀
▼ <u>M2</u>	15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg
	15820	000345-92-6	4,4'-Difluorobenzophenone	SML = 0,05 mg/kg
▼ <u>C1</u>	15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
	15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
	15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
	15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML = 6 mg/kg
	16000	000092-88-6	4,4'-Dihydroxydiphenyl	SML = 6 mg/kg
	16150	000108-01-0	Dimethylaminoethanol	SML = 18 mg/kg
	16240	000091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg in FP (expressed as NCO)
▼ <u>M5</u>	16360	000576-26-1	2,6-Dimethylphenol	SML = 0,05 mg/kg
	16450	000646-06-0	1,3-Dioxolane	SML = 0,05 mg/kg
▼ <u>C1</u>	16480	000126-58-9	Dipentaerythritol	
	16570	004128-73-8	Diphenyl ether 4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	16600	005873-54-1	Diphenylmethane 2,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	16630	000101-68-8	Diphenylmethane 4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	16660	000110-98-5	Dipropyleneglycol	
▼ <u>M5</u>	16694	013811-50-2	N,N'-Divinyl-2-imidazolidinone	QM = 5 mg/kg in FP
	16704	000112-41-4	1-Dodecene	SML = 0,05 mg/kg
▼ <u>C1</u>	16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
	16780	000064-17-5	Ethanol	
	16950	000074-85-1	Ethylene	
	16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
	16990	000107-21-1	Ethyleneglycol	► <u>M5</u> SML(T) = 30 mg/kg (3) ◀
	17005	000151-56-4	Ethyleneimine	► <u>M1</u> SML = ND (DL = 0,01 mg/kg) ◀
	17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
▼ <u>M3</u>	17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg
▼ <u>M2</u>	17160	000097-53-0	Eugenol	► <u>M5</u> SML = ND (DL = 0,02 mg/kg, analytical tolerance included) ◀

▼ M2

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
▼ <u>C1</u>	17170	Fatty acids, coco	
	17200	Fatty acids, soya	
	17230	Fatty acids, tall oil	
	17260	Formaldehyde	SML = 15 mg/kg
	17290	Fumaric acid	
	17530	Glucose	
	18010	Glutaric acid	
▼ <u>M1</u>	18070	Glutaric anhydride	
▼ <u>C1</u>	18100	Glycerol	
▼ <u>M5</u>	18220	N-Heptylaminoundecanoic acid	SML = 0,05 mg/kg (1)
▼ <u>M1</u>	18250	Hexachloroendomethylenetetrahydrophthalic acid	SML = ND (DL = 0,01 mg/kg)
	18280	Hexachloroendomethylenetetrahydrophthalic anhydride	SML = ND (DL = 0,01 mg/kg)
▼ <u>C1</u>	18310	1-Hexadecanol	
▼ <u>M1</u>	18430	Hexafluoropropylene	SML = ND (LD = 0,01 mg/kg)
▼ <u>C1</u>	18460	Hexamethylenediamine	SML = 2,4 mg/kg
	18640	Hexamethylene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	18670	Hexamethylenetetramine	► <u>M1</u> SML (T) = 15 mg/kg (expressed as formaldehyde) ◀
	000123-31-9	Hydroquinone	See '1,4-Dihydroxybenzene'
▼ <u>M5</u>	18820	1-Hexene	SML = 3 mg/kg
▼ <u>C1</u>	18880	P-Hydroxybenzoic acid	
	19000	Isobutene	
▼ <u>M5</u>	19060	Isobutyl vinyl ether	QM = 5 mg/kg in FP
	19150	Isophthalic acid	SML = 5 mg/kg
▼ <u>M2</u>	19210	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg
▼ <u>M3</u>	19270	Itaconic acid	
▼ <u>M4</u>	19460	Lactic acid	
▼ <u>M1</u>	19470	Lauric acid	
▼ <u>M4</u>	19480	Lauric acid, vinyl ester	
▼ <u>C1</u>	19510	Lignocellulose	
	19540	Maleic acid	► <u>M5</u> SML(T) = 30 mg/kg (4) ◀

▼ C1

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
19960	000108-31-6	Maleic anhydride	► <u>M5</u> SML(T) = 30 mg/kg (4) (expressed as maleic acid) ◀
	000108-78-1	Melamine	See '2,4,6-Triamino-1,3,5-triazine'
▼ <u>M5</u>	19990	000079-39-0	Methacrylamide SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
▼ <u>C1</u>	20020	000079-41-4	Methacrylic acid
▼ <u>M5</u>	20050	000096-05-9	Methacrylic acid, allyl ester SML = 0,05 mg/kg
▼ <u>M2</u>	20080	002495-37-6	Methacrylic acid, benzyl ester
▼ <u>C1</u>	20110	000097-88-1	Methacrylic acid, butyl ester
	20140	002998-18-7	Methacrylic acid, sec-butyl ester
	20170	000585-07-9	Methacrylic acid, tert-butyl ester
▼ <u>M5</u>	20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
▼ <u>C1</u>	20890	000097-63-2	Methacrylic acid, ethyl ester
	21010	000097-86-9	Methacrylic acid, isobutyl ester
	21100	004655-34-9	Methacrylic acid, isopropyl ester
	21130	000080-62-6	Methacrylic acid, methyl ester
▼ <u>M1</u>	21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol
▼ <u>M2</u>	21280	002177-70-0	Methacrylic acid, phenyl ester
▼ <u>C1</u>	21340	002210-28-8	Methacrylic acid, propyl ester
	21460	000760-93-0	Methacrylic anhydride
	21490	000126-98-7	Methacrylonitrile SML = non detectable (DL = 0,020 mg/kg, analytical tolerance included)
	21550	000067-56-1	Methanol
▼ <u>M5</u>	21730	000563-45-1	3-Methyl-1-butene QMA = 0,006 mg/6 dm ² . For use only in polypropylene.
▼ <u>M1</u>	21940	000924-42-5	N-Methylolacrylamide SML = ND (DL = 0,01 mg/kg)
▼ <u>C1</u>	22150	000691-37-2	4-Methyl-1-pentene ► <u>M1</u> SML = 0,02 mg/kg ◀
▼ <u>M5</u>	22331	025513-64-8	Mixture of (40 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane QMA = 5 mg/6 dm ²

▼ M5

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
▼ <u>M1</u>	22350	000544-63-8	Myristic acid	
▼ <u>M2</u>	22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	SML = 0,05 mg/kg
▼ <u>C1</u>	22420	003173-72-6	1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	22450	009004-70-0	Nitrocellulose	
	22480	000143-08-8	1-Nonanol	
▼ <u>M5</u>	22550	000498-66-8	Norbornene	See 'Bicyclo[2.2.1]hept-2-ene'
▼ <u>C1</u>	22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	22600	000111-87-5	1-Octanol	
	22660	000111-66-0	1-Octene	SML = 15 mg/kg
▼ <u>M1</u>	22763	000112-80-1	Oleic acid	
▼ <u>C1</u>	22780	000057-10-3	Palmitic acid	
	22840	000115-77-5	Pentaerythritol	
	22870	000071-41-0	1-Pentanol	
▼ <u>M5</u>	22937	001623-05-8	Perfluoropropyl perfluoro-vinyl ether	SML = 0,05 mg/kg
▼ <u>C1</u>	22960	000108-95-2	Phenol	
	23050	000108-45-2	1,3-Phenylenediamine	QM = 1 mg/kg in FP
		000075-44-5	Phosgene	See 'Carbonyl chloride'
	23170	007664-38-2	Phosphoric acid	
			Phthalic acid	See 'Terephthalic acid'
▼ <u>M5</u>	23175	000122-52-1	Phosphorous acid, triethyl ester	QM = ND (DL = 1 mg/kg in FP)
▼ <u>M1</u>	23200	000088-99-3	o-Phthalic acid	
	23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg)
▼ <u>C1</u>	23380	000085-44-9	Phthalic anhydride	
	23470	000080-56-8	alpha-Pinene	
	23500	000127-91-3	beta-Pinene	
▼ <u>M5</u>	23547	009016-00-6 063148-62-9	Polydimethylsiloxane (MW > 6800)	In compliance with the specifications laid down in Annex V
▼ <u>C1</u>	23590	025322-68-3	Polyethyleneglycol	
	23650	025322-69-4	Polypropyleneglycol (Molecular weight greater than 400)	
▼ <u>M4</u>	23651	025322-69-4	Polypropyleneglycol	
▼ <u>C1</u>	23740	000057-55-6	1,2-Propanediol	

▼ C1

PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
▼ <u>M5</u>	23770	000504-63-2	1,3-Propanediol	SML = 0,05 mg/kg
▼ <u>C1</u>	23800	000071-23-8	1-Propanol	
	23830	000067-63-0	2-Propanol	
	23860	000123-38-6	Propionaldehyde	
	23890	000079-09-4	Propionic acid	
▼ <u>M5</u>	23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)
▼ <u>C1</u>	23950	000123-62-6	Propionic anhydride	
	23980	000115-07-1	Propylene	
	24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP
		000120-80-9	Pyrocatechol	See '1,2-Dihydroxybenzene'
▼ <u>M2</u>	24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as pyromellitic acid)
▼ <u>C1</u>	24070	073138-82-6	Resin acids and rosin acids	
		000108-46-3	Resorcinol	See '1,3-Dihydroxybenzene'
	24100	008050-09-7	Rosin	
	24130	008050-09-7	Rosin gum	► <u>M3</u> See 'Rosin' ◀
	24160	008052-10-6	Rosin tall oil	
	24190	009014-63-5	Rosin wood	
	24250	009006-04-6	Rubber, natural	
▼ <u>M1</u>	24270	000069-72-7	Salicylic acid	
▼ <u>C1</u>	24280	000111-20-6	Sebacic acid	
▼ <u>M1</u>	24430	002561-88-8	Sebacic anhydride	
▼ <u>M2</u>	24475	001313-82-2	Sodium sulphide	
▼ <u>C1</u>	24490	000050-70-4	Sorbitol	
	24520	008001-22-7	Soybean oil	
▼ <u>M2</u>	24540	009005-25-8	Starch, edible	
▼ <u>C1</u>	24550	000057-11-4	Stearic acid	
	24610	000100-42-5	Styrene	
▼ <u>M5</u>	24760	026914-43-2	Styrenesulphonic acid	SML = 0,05 mg/kg
▼ <u>C1</u>	24820	000110-15-6	Succinic acid	
▼ <u>M1</u>	24850	000108-30-5	Succinic anhydride	
▼ <u>C1</u>	24880	000057-50-1	Sucrose	
▼ <u>M1</u>	24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	► <u>M3</u> SML = 5 mg/kg ◀

▼ M1

	PM/REF No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
	(1)	(2)	(3)	(4)
▼ <u>M2</u>	24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg
▼ <u>C1</u>	24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
▼ <u>M2</u>	24940	000100-20-9	Terephthalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as terephthalic acid)
▼ <u>C1</u>	24970	000120-61-6	Terephthalic acid, dimethyl ester	
▼ <u>M5</u>	25080	001120-36-1	1-Tetradecene	SML = 0,05 mg/kg
▼ <u>C1</u>	25090	000112-60-7	Tetraethyleneglycol	
▼ <u>M2</u>	25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg
▼ <u>C1</u>	25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
	25180	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
	25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg in FP (expressed as NCO)
	25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	► <u>M5</u> QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43) ◀
▼ <u>M5</u>	25385	000102-70-5	Triallylamine	In compliance with the specifications laid down in Annex V
▼ <u>C1</u>	25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
	25510	000112-27-6	Triethyleneglycol	
	25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
▼ <u>M1</u>	25910	024800-44-0	Tripropyleneglycol	
▼ <u>M5</u>	25927	027955-94-8	1,1,1-Tris(4-hydroxyphenyl)ethane	QM = 0,5 mg/kg in FP. For use only in polycarbonates
▼ <u>C1</u>	25960	000057-13-6	Urea	
	26050	000075-01-4	Vinyl chloride	See Council Directive 78/142/EEC
	26110	000075-35-4	Vinylidene chloride	QM = 5 mg/kg in FP or SML = not detectable (DL = 0,05 mg/kg)
▼ <u>M3</u>	26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg
▼ <u>M5</u>	26155	001072-63-5	1-Vinylimidazole	QM = 5 mg/kg in FP
	26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
	26360	007732-18-5	Water	In compliance with Directive 98/83/EC
	26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 2 mg/kg in FP

▼ M5▼ C1

SECTION B

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY CONTINUE TO BE USED PENDING A DECISION ON INCLUSION IN SECTION A

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
	000542-02-9	Acetoguanamine	See '2,4-Diamino-6-methyl-1,3,5-triazine'
▼ <u>M2</u>	10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled
	10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled
	10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled
	10599/93	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled
▼ <u>M5</u>			
▼ <u>C1</u>	11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester
	11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester
▼ <u>M5</u>			
▼ <u>C1</u>	12910	001732-10-1	Azelaic acid, dimethyl ester
	13030	000528-44-9	1,2,4-Benzenetricarboxylic acid
▼ <u>M5</u>			See 'Trimellitic acid'
▼ <u>C1</u>			
	000091-76-9	Benzoguanamine	See '2,4-Diamino-6-phenyl-1,3,5-triazine'
	13570	000080-09-1	Bisphenol S
	13720	000110-63-4	1,4-Butanediol
▼ <u>M5</u>			
▼ <u>C1</u>	13810	000505-65-7	1,4-Butanediol formal
▼ <u>M1</u>	13932	000598-32-3	3-Buten-2-ol
▼ <u>M5</u>			
▼ <u>C1</u>	14260	000502-44-3	Caprolactone
	14470	000115-28-6	Chlorendic acid
	14800	003724-65-0	Crotonic acid
▼ <u>M5</u>			See 'Hexachloroendo-methylene-tetrahydrophthalic acid'
▼ <u>C1</u>	15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine
	15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane

▼ C1

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
15400	003236-54-2	1,6-Diamino-2,4,4-trimethyl-hexane	
15610	000080-07-9	4,4'-Dichlorodiphenyl sulphone	
15730	000077-73-6	Dicyclopentadiene	
16090	000080-09-1	4,4'-Dihydroxydiphenyl sulphone	
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	
▼ M5			
▼ C1			
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	
▼ M5			
▼ C1			
16540	000102-09-0	Diphenyl carbonate	
16690	001321-74-0	Divinylbenzene	► M5 QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) ◀
▼ M1			
16697	000693-23-2	Dodecanedioic acid	
▼ C1			
17110	016219-75-3	5-Ethylidenebicyclo[2.2.1]-hept-2-ene	
▼ M5			
▼ C1			
18370	000592-45-0	1,4-Hexadiene	
▼ M1			
18441	000085-42-7	Hexahydrophthalic anhydride	
▼ C1			
18700	000629-11-8	1,6-Hexanediol	
▼ M5			
▼ C1			
19180	000099-63-8	Isophthalic acid dichloride	
19240	000078-79-5	Isoprene	See '2-Methyl-1,3-butadiene'
▼ M1			
19490	000947-04-6	Lauro lactam	
▼ C1			
19570	000999-21-3	Maleic acid, diallyl ester	
19600	000105-76-0	Maleic acid, dibutyl ester	
▼ M5			
▼ C1			
20260	000101-43-9	Methacrylic acid, cyclohexyl ester	
20380	001189-08-8	Methacrylic acid, diester with 1,3-butanediol	
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	

▼ C1

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
▼ M5			
▼ C1			
20590	000106-91-2	Methacrylic acid, 2,3-epoxy-propyl ester	► M5 QM(T) = 5 mg/kg in FP (expressed as epoxy group, molecular weight = 43) ◀
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	
21520	001561-92-8	Methallylsulphonic acid, sodium salt	QM = 5 mg/kg in FP
21640	000078-79-5	2-Methyl-1,3-butadiene	
▼ M5			
▼ C1			
21820	000505-65-7	1,4-(Methylenedioxy)butane	See '1,4-Butanediol formal'
21970	000923-02-4	N-Methylmethacrylamide	
22210	000098-83-9	alpha-Methylstyrene	
22360	001141-38-4	2,6-Naphtalenedicarboxylic acid	
	000126-30-7	Neopentylglycol	See '2,2-Dimethyl-1,3-propanediol'
▼ M5			
▼ C1			
22540	000498-66-8	Norbornene	See 'Bicyclo[2.2.1]hept-2-ene'
22720	000140-66-9	4-tert-Octylphenol	► M5 See '4-(1,1,3,3-Tetramethylbutyl)phenol' ◀
22900	000109-67-1	1-Pentene	
▼ M5			
▼ C1			
23140	000092-69-3	Phthalic acids	See 'Iso- or o-phthalic acid'
▼ M5			
▼ C1			
24370	000106-79-6	Sebacic acid, dimethyl ester	
▼ M5			
▼ M1			
25380		Trialkyl (C5-C15) acetic acid, vinyl ester (= vinyl versatate)	
▼ C1			
25390	000101-37-1	Triallyl cyanurate	
25450	026896-48-0	Tricyclodecanedimethanol	
25540	000528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP
25550	000552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	
25900	000110-88-3	Trioxane	
	000102-71-6	Tris(2-hydroxyethyl)amine	See 'Triethanolamine'

▼ C1

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
▼ <u>M5</u>			
▼ <u>C1</u>			
26230	000088-12-0	Vinylpyrrolidone	
26290	000622-97-9	<i>p</i> -Vinyltoluene	See ' <i>p</i> -Methylstyrene'
26320	000105-67-9	<i>m</i> -Xylenol	See '2,4-Dimethylphenol'
	000526-75-0	<i>o</i> -Xylenol	See '2,3-Dimethylphenol'
	000095-87-4	<i>p</i> -Xylenol	See '2,5-Dimethylphenol'
▼ <u>M1</u>			
▼ <u>M2</u>			
▼ <u>M3</u>			
▼ <u>M4</u>			

▼ **M3***ANNEX III***INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE
MANUFACTURE OF PLASTICS MATERIALS AND ARTICLES****General introduction**

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

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

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorized acids, phenols or alcohols which are also authorized. However, names containing ‘...acid(s), salts’ appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases, the meaning of the term ‘salts’ is ‘salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc’.
3. The list does not include the following substances although they may be present:

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

▼ **M5**

- Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or to the polymer.

▼ **M3**

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.

▼ **M3****Incomplete list of additives**

PM/Ref No	CAS No	Name	► M5 Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
30000	000064-19-7	Acetic acid		
30045	000123-86-4	Acetic acid, butyl ester		
▼ M5	30080	004180-12-5	Acetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
▼ M3	30140	000141-78-6	Acetic acid, ethyl ester	
	30280	000108-24-7	Acetic anhydride	
	30295	000067-64-1	Acetone	
	30370	—	Acetylacetic acid, salts	
	30400	—	Acetylated glycerides	
▼ M5	30610	—	Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	
	30612	—	Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic, and their mono-, di- and triglycerol esters	
▼ M3	30960	—	Acids aliphatic monocarboxylic (C ₆ -C ₂₂) esters with polyglycerol	
	31328	—	Acids, fatty, from animal or vegetable food fats and oils	
▼ M5	31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]phenyl ester	SML = 5 mg/kg
▼ M3	31730	000124-04-9	Adipic acid	
	33120	—	Alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₂₄)	
	33350	009005-32-7	Alginic acid	
▼ M5	33801	—	n-Alkyl(C10-C13)benzenesulphonic acid	SML = 30 mg/kg
	34240	—	Alkyl(C10-C20)sulphonic acid,	SML = 6 mg/kg. Authorised until 1 January 2002
▼ M4	34281	—	Alkyl(C ₈ -C ₂₂) sulphonic acids, linear, primary, with an even number of carbon atoms	
	34475	—	Aluminium calcium hydroxide phosphite, hydrate	
▼ M3	34480	—	Aluminium fibers, flakes and powders	
	34560	021645-51-2	Aluminium hydroxide	
	34690	011097-59-9	Aluminium magnesium carbonate hydroxide	

▼ M3

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
34720	001344-28-1	Aluminium oxide		
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether		
35320	007664-41-7	Ammonia		
35440	012124-97-9	Ammonium bromide		
35600	001336-21-6	Ammonium hydroxide		
35840	000506-30-9	Arachidic acid		
35845	007771-44-0	Arachidonic acid		
36000	000050-81-7	Ascorbic acid		
36080	000137-66-6	Ascorbyl palmitate		
36160	010605-09-1	Ascorbyl stearate		
▼ <u>M5</u>	36640	000123-77-3	Azodicarbonamide	For use only as a blowing agent
▼ <u>M3</u>	36880	008012-89-3	Beeswax	
	36960	003061-75-4	Behenamide	
	37040	000112-85-6	Behenic acid	
	37280	001302-78-9	Bentonite	
▼ <u>M5</u>	37360	000100-52-7	Benzaldehyde	In compliance with note 10 in Annex VI
▼ <u>M3</u>	37600	000065-85-0	Benzoic acid	
	37680	000136-60-7	Benzoic acid, butyl ester	
	37840	000093-89-0	Benzoic acid, ethyl ester	
	38080	000093-58-3	Benzoic acid, methyl ester	
	38160	002315-68-6	Benzoic acid, propyl ester	
▼ <u>M5</u>	38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene	In compliance with the specifications laid down in Annex V
	38510	136504-96-6	1,2-Bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	SML = 5 mg/kg
▼ <u>C2</u>	38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene	SML = 0,05 mg/kg (1)
▼ <u>M5</u>	38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	SML = 5 mg/kg (sum of phosphite and phosphate)
	38879	135861-56-2	Bis(3,4-dimethylbenzylidene)sorbitol	
▼ <u>M3</u>	38950	079072-96-1	Bis (4-ethylbenzylidene) sorbitol	
▼ <u>M5</u>	39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	SML = 1,8 mg/kg
▼ <u>C2</u>	39815	182121-12-6	9,9-Bis(methoxymethyl)-fluorene	QMA = 0,05 mg/6 dm ²

▼ C2

	PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
	(1)	(2)	(3)	(4)
▼ <u>M3</u>	39890	► <u>M5</u> 087826-41-3 ◀	Bis (methylbenzylidene) sorbitol	
		► <u>M5</u> 069158-41-4 ◀		
		► <u>M5</u> 054686-97-4 ◀		
		► <u>M5</u> 081541-12-0 ◀		
▼ <u>M5</u>	40120	—	Bis(polyethyleneglycol)hy- droxymethylphosphonate	SML = 0,6 mg/kg. Authorised until 1 January 2002
▼ <u>M3</u>	40400	010043-11-5	Boron nitride	
	40570	000106-97-8	Butane	
	41040	005743-36-2	Calcium butyrate	
	41280	001305-62-0	Calcium hydroxide	
	41520	001305-78-8	Calcium oxide	
	41600	012004-14-7	Calcium sulphoaluminate	
▼ <u>M5</u>	41680	000076-22-2	Camphor	In compliance with note 10 in Annex VI
▼ <u>M3</u>		037293-22-4		
	41760	008006-44-8	Candelilla wax	
	41960	000124-07-2	Caprylic acid	
	42160	000124-38-9	Carbon dioxide	
▼ <u>M5</u> ▼ <u>C2</u>	42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
▼ <u>M3</u>	42500	—	Carbonic acid, salts	
	42640	009000-11-7	Carboxymethylcellulose	
	42720	008015-86-9	Carnauba wax	
	42800	009000-71-9	Casein	
	42960	064147-40-6	Castor oil, dehydrated	
	43200	—	Castor oil, mono- and digly- cerides	
	43280	009004-34-6	Cellulose	
	43300	009004-36-8	Cellulose acetate butyrate	
	43360	068442-85-3	Cellulose, regenerated	
	43440	008001-75-0	Ceresin	
▼ <u>M5</u>	43515	—	Chlorides of choline esters of coconut oil fatty acids	QMA = 0,9 mg/6 dm ²
▼ <u>M3</u>	44160	000077-92-9	Citric acid	

▼ M3

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
44640	000077-93-0	Citric acid, triethyl ester		
▼ <u>M5</u>	45195	Copper bromide	SML(T) = 30 mg/kg (7) (expressed as copper)	
45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg (7) (expressed as copper) and SML = 1 mg/kg (expressed as iodine)	
▼ <u>M3</u>	45280	—	Cotton fibers	
▼ <u>M5</u>	45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 0,05 mg/kg (1)
▼ <u>M3</u>	45560	014464-46-1	Cristobalite	
45760	000108-91-8	Cyclohexylamine		
45920	009000-16-2	Dammar		
45940	000334-48-5	n-Decanoic acid		
46070	010016-20-3	alpha-Dextrin		
46080	007585-39-9	beta-Dextrin		
46375	061790-53-2	Diatomaceous earth		
▼ <u>M4</u>	46380	068855-54-9	Diatomaceous earth, soda ash flux-calcined	
▼ <u>M3</u>	46480	032647-67-9	Dibenzylidene sorbitol	
46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester		
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester		
46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester		
▼ <u>M5</u>	46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt	SML = 6 mg/kg
▼ <u>M3</u>	47440	000461-58-5	Dicyanodiamide	
▼ <u>M5</u> ▼ <u>C2</u>	47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg (3)
▼ <u>M5</u>	48460	000075-37-6	1,1-Difluoroethane	
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	SML = 1 mg/kg	
▼ <u>M3</u>	49540	000067-68-5	Dimethyl sulphoxide	
51200	000126-58-9	Dipentaerythritol		
▼ <u>M5</u> ▼ <u>C2</u>	51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)-phenol	SML = 0,05 mg/kg

▼ C2

	PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
	(1)	(2)	(3)	(4)
▼ <u>M3</u>	51760	025265-71-8 000110-98-5	Dipropyleneglycol	
	52640	016389-88-1	Dolomite	
▼ <u>M4</u>	52720	000112-84-5	Erucamide	
▼ <u>M3</u>	52730	000112-86-7	Erucic acid	
	52800	000064-17-5	Ethanol	
	53270	037205-99-5	Ethylcarboxymethylcellulose	
	53280	009004-57-3	Ethylcellulose	
	53360	000110-31-6	N,N'-Ethylenebisoleamide	
	53440	005518-18-3	N,N'-Ethylenebispalmitamide	
	53520	000110-30-5	N,N'-Ethylenebisstearamide	
	53600	000060-00-4	Ethylenediaminetetraacetic acid	
▼ <u>M5</u> ▼ <u>C2</u>	53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
▼ <u>M5</u>	53650	000107-21-1	Ethylene glycol	SML(T) = 30 mg/kg (3)
▼ <u>M3</u>	54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	
	54260	009004-58-4	Ethylhydroxyethylcellulose	
	54270	—	Ethylhydroxymethylcellulose	
	54280	—	Ethylhydroxypropylcellulose	
▼ <u>M5</u>	54300	118337-09-0	2,2'Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	SML = 6 mg/kg
▼ <u>M3</u>	54450	—	Fats and oils, from animal or vegetable food sources	
	54480	—	Fats and oils, hydrogenated, from animal or vegetable food sources	
▼ <u>M5</u>	54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [=Poly(1-hydroxynaphthyl-methane)]	SML = 0,05 mg/kg
▼ <u>M3</u>	55040	000064-18-6	Formic acid	
	55120	000110-17-8	Fumaric acid	
	55190	029204-02-2	Gadoleic acid	
	55440	009000-70-8	Gelatin	
▼ <u>M4</u>	55520	—	Glass fibres	
	55600	—	Glass microballs	
▼ <u>M3</u>	55680	000110-94-1	Glutaric acid	
	55920	000056-81-5	Glycerol	
	56020	099880-64-5	Glycerol dibehenate	

▼ **M3**

PM/Ref No	CAS No	Name	► M5 Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
56360	—	Glycerol, esters with acetic acid	
▼ M4			
56486	—	Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C ₁₄ -C ₁₈) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C ₁₆ -C ₁₈)	
▼ M3			
56487	—	Glycerol, esters with butyric acid	
56490	—	Glycerol, esters with erucic acid	
56495	—	Glycerol, esters with 12-hydroxystearic acid	
56500	—	Glycerol, esters with lauric acid	
56510	—	Glycerol, esters with linoleic acid	
56520	—	Glycerol, esters with myristic acid	
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
56565	—	Glycerol, esters with nonanoic acid	
56570	—	Glycerol, esters with propionic acid	
56580	—	Glycerol, esters with ricinoleic acid	
56585	—	Glycerol, esters with stearic acid	
56610	030233-64-8	Glycerol monobehenate	
56720	026402-23-3	Glycerol monoheanoate	
56800	030899-62-8	Glycerol monolaurate diacetate	
56880	026402-26-6	Glycerol monooleate	
57040	—	Glycerol monooleate, ester with ascorbic acid	
57120	—	Glycerol monooleate, ester with citric acid	
57200	—	Glycerol monopalmitate, ester with ascorbic acid	
57280	—	Glycerol monopalmitate, ester with citric acid	
57600	—	Glycerol monostearate, ester with ascorbic acid	
57680	—	Glycerol monostearate, ester with citric acid	
▼ M5			
57800	018641-57-1	Glycerol tribehenate	
▼ M3			
57920	000620-67-7	Glycerol triheptanoate	

▼ M3

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
58300	—	Glycine, salts		
58320	007782-42-5	Graphite		
58400	009000-30-0	Guar gum		
58480	009000-01-5	Gum arabic		
58720	000111-14-8	Heptanoic acid		
59360	000142-62-1	Hexanoic acid		
59760	019569-21-2	Huntite		
59990	007647-01-0	Hydrochloric acid		
60030	012072-90-1	Hydromagnesite		
60080	012304-65-3	Hydrotalcite		
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester		
60180	004191-73-5	4-Hydroxybenzoic acid, isopropyl ester		
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester		
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester		
▼ <u>M5</u> ▼ <u>C2</u>	60480	003864-99-1	2-(2-Hydroxy-3,5-di-tert-butyl-phenyl)-5-chlorobenzotriazole	SML = 30 mg/kg
▼ <u>M3</u>	60560	009004-62-0	Hydroxyethylcellulose	
	60880	009032-42-2	Hydroxyethylmethylcellulose	
	61120	009005-27-0	Hydroxyethyl starch	
	61390	037353-59-6	Hydroxymethylcellulose	
	61680	009004-64-2	Hydroxypropylcellulose	
	61800	009049-76-7	Hydroxypropyl starch	
	61840	000106-14-9	12-Hydroxystearic acid	
	62140	006303-21-5	Hypophosphorous acid	
	62240	001332-37-2	Iron oxide	
	62450	000078-78-4	Isopentane	
	62640	008001-39-6	Japan Wax	
	62720	001332-58-7	Kaolin	
	62800	—	Kaolin, calcined	
	62960	000050-21-5	Lactic acid	
	63040	000138-22-7	Lactic acid, butyl ester	
	63280	000143-07-7	Lauric acid	
	63760	008002-43-5	Lecithin	
	63840	000123-76-2	Levulinic acid	
	63920	000557-59-5	Lignoceric acid	
	64015	000060-33-3	Linoleic acid	
	64150	028290-79-1	Linolenic acid	
	64500	—	Lysine, salts	
	64640	001309-42-8	Magnesium hydroxide	
	64720	001309-48-4	Magnesium oxide	

▼ **M3**

PM/Ref No	CAS No	Name	► M5 Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
65020	006915-15-7	Malic acid		
65040	000141-82-2	Malonic acid		
65520	000087-78-5	Mannitol		
66200	037206-01-2	Methylcarboxymethylcellulose		
66240	009004-67-5	Methylcellulose		
▼ M5	66560	004066-02-8	2,2'Methylenebis(4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg (6)
	66580	000077-62-3	2,2'Methylenebis[4-methyl-6-(1-methylcyclo-hexyl)-phenol]	SML(T) = 3 mg/kg (6)
▼ M3	66640	009004-59-5	Methylethylcellulose	
	66695	—	Methylhydroxymethylcellulose	
	66700	009004-65-3	Methylhydroxypropylcellulose	
▼ M5 ▼ C2	66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
▼ M3	67120	012001-26-2	Mica	
▼ M5	67170	—	Mixture of (80 to 100 % w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0 to 20 %w/w)5,7-di-tert-butyl-3-(2,3-di-methylphenyl)-2(3H)-benzofuranone	SML = 5 mg/kg
	67180	—	Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester	SML = 5 mg/kg (1)
▼ M3	67200	001317-33-5	Molybdenum disulphide	
	67840	—	Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	
	67850	008002-53-7	Montan wax	
	67891	000544-63-8	Myristic acid	
	68040	003333-62-8	7-[2-H-Naphto-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
	68125	► M5 037244-96-5 ◀	Nepheline syenite	
▼ M5	68145	080410-33-9	2,2',2''-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite]	SML = 5 mg/kg (sum of phosphite and phosphate)

▼ M5

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
▼ <u>M4</u>	68960	000301-02-0	Oleamide	
▼ <u>M3</u>	69040	000112-80-1	Oleic acid	
	69760	000143-28-2	Oleyl alcohol	
	70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	
	70240	012198-93-5	Ozokerite	
	70400	000057-10-3	Palmitic acid	
	71020	000373-49-9	Palmitoleic acid	
	71440	009000-69-5	Pectin	
	71600	000115-77-5	Pentaerythritol	
▼ <u>M5</u>	71635	025151-96-6	Pentaerythritol dioleate	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
▼ <u>M3</u>	71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	
	71720	000109-66-0	Pentane	
	72640	007664-38-2	Phosphoric acid	
▼ <u>M5</u> ▼ <u>C2</u>	73720	0000115-96-8	Phosphoric acid, trichloroethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
▼ <u>M5</u>	74010	145650-60-8	Phosphorous acid, bis (2,4-di-tert-butyl-6-methylphenyl) ethyl ester	SML = 5 mg/kg (sum of phosphite and phosphate)
▼ <u>M3</u>	74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	
	74480	000088-99-3	o-Phthalic acid	
	76320	000085-44-9	Phthalic anhydride	
▼ <u>M5</u>	76721	009016-00-6 063148-62-9	Polydimethylsiloxane (MW > 6800)	In compliance with the specifications laid down in Annex V
▼ <u>C2</u>	76865	—	Polyesters of 1,2-propanediol and/or 1,3- and 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol	SML = 30 mg/kg
▼ <u>M3</u>	76960	025322-68-3	Polyethyleneglycol	
	77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil	

▼ **M3**

PM/Ref No	CAS No	Name	► M5 Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
77702	—	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C ₆ -C ₂₂), and their ammonium and sodium sulphates	
▼ M5			
77895	068439-49-6	Polyethyleneglycol(EO = 2-6) monoalkyl(C16-C18) ether	SML = 0,05 mg/kg
▼ M3			
79040	009005-64-5	Polyethyleneglycol sorbitan monolaureate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl(C ₂ -C ₄)dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
▼ M4			
80800	025322-69-4	Polypropyleneglycol	
▼ M5			
81515	087189-25-1	Poly(zinc glycerolate)	
▼ M3			
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	
▼ M5			
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 30 mg/kg (7) (expressed as copper); SML = 48 mg/kg (expressed as iron)
▼ M3			
81840	000057-55-6	1,2-Propanediol	
81882	000067-63-0	2-Propanol	
82000	000079-09-4	Propionic acid	
82080	009005-37-2	1,2-Propyleneglycol alginate	
82240	022788-19-8	1,2-Propyleneglycol dilaurate	
82400	000105-62-4	1,2-Propyleneglycol dioleate	
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	
82720	006182-11-2	1,2-Propyleneglycol distearate	
82800	027194-74-7	1,2-Propyleneglycol mono-laurate	
82960	001330-80-9	1,2-Propyleneglycol mono-oleate	
83120	029013-28-3	1,2-Propyleneglycol mono-palmitate	
83300	001323-39-3	1,2-Propyleneglycol mono-stearate	

▼ M3

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀
(1)	(2)	(3)	(4)
83320	—	Propylhydroxyethylcellulose	
83325	—	Propylhydroxymethylcellulose	
83330	—	Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
83610	073138-82-6	Resin acids and rosin acids	
83840	008050-09-7	Rosin	
84000	008050-31-5	Rosin, ester with glycerol	
84080	008050-26-8	Rosin, ester with pentaerythritol	
84210	065997-06-0	Rosin, hydrogenated	
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	
84560	009006-04-6	Rubber, natural	
84640	000069-72-7	Salicylic acid	
▼ <u>M5</u>			
85360	000109-43-3	Sebacic acid, dibutyl ester	
▼ <u>M3</u>			
85600	—	Silicates, natural	
▼ <u>M5</u>			
85610	—	Silicates, natural, silanated (with the exception of asbestos)	
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0,6 mg/kg (8) (expressed s lithium)
▼ <u>M3</u>			
85980	—	Silicic acid, salts	
86000	—	Silicic acid, silylated	
86160	000409-21-2	Silicon carbide	
86240	007631-86-9	Silicon dioxide	
▼ <u>M5</u>			
86285	—	Silicon dioxide, silanated	
▼ <u>M3</u>			
86560	007647-15-6	Sodium bromide	
86720	001310-73-2	Sodium hydroxide	
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	
87520	062568-11-0	Sorbitan monobehenate	
87600	001338-39-2	Sorbitan monolaurate	
87680	001338-43-8	Sorbitan monooleate	
87760	026266-57-9	Sorbitan monopalmitate	
87840	001338-41-6	Sorbitan monostearate	
87920	061752-68-9	Sorbitan tetrastearate	

▼ **M3**

PM/Ref No	CAS No	Name	► M5 Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
88080	026266-58-0	Sorbitan trioleate		
88160	054140-20-4	Sorbitan tripalmitate		
88240	026658-19-5	Sorbitan tristearate		
88320	000050-70-4	Sorbitol		
88600	026836-47-5	Sorbitol monostearate		
▼ M5	88640	008013-07-8	Soybean oil, epoxidised	In compliance with the specifications laid down in Annex V
▼ M3	88800	009005-25-8	Starch, edible	
	88880	068412-29-3	Starch, hydrolysed	
▼ M4	88960	000124-26-5	Stearamide	
▼ M3	89040	000057-11-4	Stearic acid	
▼ M5	89200	007617-31-4	Stearic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
	89440	—	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/kg (3)
▼ M3	90720	058446-52-9	Stearoylbenzoylmethane	
	90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	
	90960	000110-15-6	Succinic acid	
	91200	000126-13-6	Sucrose acetate isobutyrate	
	91360	000126-14-7	Sucrose octaacetate	
	91840	007704-34-9	Sulphur	
	91920	007664-93-9	Sulphuric acid	
▼ M5	92030	010124-44-4	Sulphuric acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
▼ M3	92080	014807-96-6	Talc	
	92160	000087-69-4	Tartaric acid	
	92195	—	Taurine, salts	
	92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	
	92350	000112-60-7	Tetraethyleneglycol	
	92640	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
▼ M5	92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadspiro[5.1.11.2]-heneicosan-21-one, polymer	SML = 5 mg/kg
	92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	SML = 6 mg/kg
▼ M3	93440	013463-67-7	Titanium dioxide	
	93520	000059-02-9	alpha-Tocopherol	
		010191-41-0		

▼ M3

PM/Ref No	CAS No	Name	► <u>M5</u> Restrictions and/or specifications ◀	
(1)	(2)	(3)	(4)	
93680	009000-65-1	Tragacanth gum		
94320	000112-27-6	Triethyleneglycol		
▼ <u>M5</u> ▼ <u>C2</u>	94960	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
▼ <u>M3</u>	95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	
▼ <u>M5</u>	95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0,6 mg/kg (8) (expressed as lithium)
	95855	007732-18-5	Water	In compliance with Directive 98/83/EC
	95859	—	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
	95883	—	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
▼ <u>M3</u>	95905	013983-17-0	Wollastonite	
	95920	—	Wood flour and fibres, untreated	
	95935	011138-66-2	Xanthan gum	
	96190	020427-58-1	Zinc hydroxide	
	96240	001314-13-2	Zinc oxide	
	96320	001314-98-3	Zinc sulphide	

▼ M5

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

PM/Ref No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
▼ <u>C2</u> 18888	80181-31-3	3-hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer	SML = 0,05 mg/kg for crotonic acid (as impurity) and in compliance with the specifications laid down in Annex IV

▼ M5

ANNEX V

SPECIFICATIONS

Part A: General specifications

(to be fixed later)

Part B: Other specifications

PM/Ref No	Other specifications
18888	<p>3-HYDROXYBUTANOIC ACID-3-HYDROXPENTANOIC ACID, COPOLYMER</p> <p><i>Definition</i></p> <p>These copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat-treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt-formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.</p> <p>— Chemical name Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)</p> <p>— CAS No 80181-31-3</p> <p>— Structural formula</p> $\begin{array}{c} \text{CH}_3 \\ \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C})_m - (\text{O}-\text{CH}-\text{CH}_2-\text{C})_n \\ \quad \quad \quad \quad \quad \quad \quad \quad \quad \\ \text{CH}_3 \quad \quad \quad \text{O} \quad \quad \quad \text{CH}_2 \quad \quad \quad \text{O} \end{array}$ <p>where $n/(m+n)$ greater than 0 and less or equal to 0,25</p> <p>— Average molecular weight Not less than 150 000 daltons (measured by gel permeation chromatography).</p> <p>— Assay Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids</p> <p><i>Description</i></p> <p>White to off-white powder after isolation</p> <p><i>Characteristics</i></p> <p>— Identification tests:</p> <p>— Solubility Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.</p> <p>— Migration The migration of crotonic acid should not exceed 0,05 mg/kg food.</p>

▼ C2▼ M5

▼ **M5**

PM/Ref No	Other specifications
	<ul style="list-style-type: none"> — Purity Prior to granulation the raw material copolymer powder must contain: — Nitrogen Not more than 2 500 mg/kg of plastic — Zinc Not more than 100 mg/kg of plastic — Copper Not more than 5 mg/kg of plastic — Lead Not more than 2 mg/kg of plastic — Arsenic Not more than 1 mg/kg of plastic — Chromium Not more than 1 mg/kg of plastic.
23547	POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (= 100 centistokes) at 25 °C
25385	TRIALLYLAMINE 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.
38320	4-(2-BENZOXAZOLYL)-4'-(5-METHYL-2-BENZOXAZOLYL) STILBENE Not more than 0,05 % w/w (quantity of substance used/quantity of the formulation)
▼ C2	76721 POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity 100×10^{-6} m ² /s (= 100 centistokes) at 25 °C
▼ M5	88640 SOYBEAN OIL, EPOXIDISED Oxirane < 8 %, iodine number < 6
95859	WAXES, REFINED, DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEEDSTOCKS The product should have the following specifications: <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w) — Viscosity not less than 11×10^{-6} m²/s (= 11 centistokes) at 100 °C — Average molecular weight not less than 500
95883	WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS The product should have the following specifications: <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w) — Viscosity not less than $8,5 \times 10^{-6}$ m²/s (= 8,5 centistokes) at 100 °C — Average molecular weight not less than 480

▼M5

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 PM/ REF Nos: 10060 and 23920.
- (3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/ REF Nos: 15760, 16990, 47680, 53650, 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 PM/ REF Nos: 19540, 19960.
- (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 PM/ REF Nos: 14200, 14230.
- (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 PM/ REF Nos: 66560 and 66580.
- (7) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/ REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200, 92030.
- (8) 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 PM/ REF Nos: 85840 and 95725.
- (9) 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:
 - (a) Badge (=2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether:
 - (b) Badge.H₂O.
 - (d) Badge.HCl.
 - (e) Badge.2HCl
 - (f) Badge.H₂O.HCl

However in aqueous food simulants, the SML(T) should also include Badge.2H₂O (c) unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five abovementioned substances (a)(b)(d)(e)(f) cannot exceed 1 mg/kg.
- (10) 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.