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► B 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:

		Offi	cial Journ	al
		No	page	date
► <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>M4</u>	Commission Directive 96/11/EC of 5 March 1996	L 61	26	12.3.1996

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▶<u>C1</u> Corrigendum, OJ L 349, 13.12.1990, p. 26 (90/128)

COMMISSION DIRECTIVE

of 23 February 1990

relating to plastic 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 $\frac{82}{711}$ (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;

Whereas Council Directive 78/142/EEC (4) 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

OJ No L 40, 11. 2. 1989, p. 38.
 OJ No L 297, 23. 10. 1982, p. 26.
 OJ No L 372, 31. 12. 1985, p. 14.

^{(&}lt;sup>4</sup>) OJ No L 44, 15. 2. 1978, p. 15.

80/766/EEC (¹) and 81/432/EEC (²) establish the Community methods of analysis for controlling these limits;

Whereas Commission Directive 80/590/EEC (³) 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 (⁴), as amended by Directive 86/ 388/EEC (⁵);
- (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;
- (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

⁽¹⁾ OJ No L 213, 16. 8. 1980, p. 42.

^{(&}lt;sup>2</sup>) OJ No L 167, 24. 6. 1981, p. 6.
(³) OJ No L 151, 19. 6. 1980, p. 21.

⁽⁴⁾ OJ No L 123, 11. 5. 1983, p. 31.

^{(&}lt;sup>5</sup>) OJ No L 228, 14. 8. 1986, p. 32.

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.

▼<u>M4</u>

▼C1

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.

▼<u>C1</u>

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,
- products obtained by means of bacterial fermentation,
- adhesives and adhesion promoters,
- printing inks.

▼M3

Article 3a

An incomplete list of additives which may be used for the manufacture of plastics materials and articles is set out in Annex III.

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.

▼<u>M2</u>

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.

▼<u>C1</u>

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.

- 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.

ANNEX I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLI-ANCE WITH THE MIGRATION LIMITS

General provisions

- 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;
- a_1 is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test;
- a_2 is the surface area in dm² of the material or article in real conditions of use;
- q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.
- 3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.

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

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

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

- 4. In accordance with the provisions set out in Article 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 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 $\blacktriangleright \underline{M3}$ as regards the purity criteria \blacktriangleleft .
- 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,
 - column 4 (Restrictions). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the 'residual' substance in the material or article (QM),
 - any other restriction specifically mentioned.
- 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;

▼C1		
_	FP =	finished material or article;
▼ <u>M1</u>	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.
▼C1		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.
▼ <u>C1</u>		
	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.
▼ <u>M2</u>		
		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.
▼ <u>C1</u>		
	SML =	specific migration limit in food or in food simulant, unless it is specified otherwise.
▼ <u>M1</u>		
		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.
▼ <u>C1</u>		
▼ <u>M2</u>	SML (T) =	specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated.
▼ <u>C1</u>		For the purpose of this Directive 'SML (T)' menas 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.

SECTION A

LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES

 PM/REF No	CAS No	Name	Restrictions
 (1)	(2)	(3)	(4)
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	

▼C1 PM/REF No CAS No Name Restrictions (1) (2) (3) (4) 10210 000074-86-2 Acetylene ▼<u>M1</u> 10630 000079-06-1 Acrylamide SML = ND (DL= 0.01 mg/kg▼M3 10660 015214-89-8 SML = 0.05 mg/kg2-Acrylamido-2-methylpropanesulphonic acid **▼**C1 10690 000079-10-7 Acrylic acid ▼M2 10750 002495-35-4 Acrylic acid, benzyl ester **▼**C1 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 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 ▼M1 12280 002035-75-8 Adipic anhydride **▼**C1 12310 Albumin 12340 Albumin, coagulated by formaldehyde 12375 Alcohols aliphatic, monohydric, saturated, linear, primary (C4-C22) ▼M1 12670 002855-13-2 1-Amino-3-aminomethyl-3,5,5-SML = 6 mg/kgtrimethylcyclohexane 12788 002432-99-7 11-Aminoundecanoic acid \blacktriangleright <u>M2</u> SML = 5 mg/kg \triangleleft ▼<u>M3</u> 12789 007664-41-7 Ammonia ▼C1 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

▼C1

▼ C1				
	PM/REF No	CAS No	Name	Restrictions
_	(1)	(2)	(3)	(4)
	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'
	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	QM = 1 mg/kg de FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
		000110-98-5	Bis(hydroxypropyl) ether	See 'Dipropyleneglycol'
		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 anhy- dride)	See 13530
▼ <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	
	13840	000071-36-3	1-Butanol	
	13870	000106-98-9	1-Butene	
	13900	000107-01-7	2-Butene	
	14110	000123-72-8	Butyraldehyde	
	14140	000107-92-6	Butyric acid	
	14170	000106-31-0	Butyric anhydride	
	14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg
	14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg (expressed as caprolactam)
	14320	000124-07-2	Caprylic acid	
	14350	000630-08-0	Carbon monoxide	OM 1 m /les in FD
▼M2	14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
▼ <u>M3</u>				
▼C1	14411	008001-79-4	Castor oil	
_	14500	009004-34-6	Cellulose	

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
14530	007782-50-5	Chlorine	
	000106-89-8	1-Chloro-2,3-epoxypropane	See 'Epichlorhydrin'
14680	000077-92-9	Citric acid	
14710	000108-39-4	<i>m</i> -Cresol	
14740	000095-48-7	o-Cresol	
14770	00106-44-5	p-Cresol	
	000105-08-8	1,4-Cyclohexanedimethanol	See '1,4-Bis(hydroxymethyl) cyclohexane'
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
15070	001647-16-1	1,9-Decadiene	SML = 0.05 mg/kg
15095	000334-48-5	Decanoic acid	
15100	000112-30-1	1-Decanol	
	000107-15-3	1,2-Diaminoethane	See 'Ethylenediamine'
	000124-09-4	1,6-Diaminohexane	See 'Hexamethylenediamine
15250	000110-60-1	1,4-Diaminobutane	
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15700	005124-30-1	Dicyclohexylmethane-4,4'-diiso- cyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg alone with ethyleneglycol
15700	000111 40 0	Distladou striourin s	SML = 5 mg/kg
15790 15820	000111-40-0 000345-92-6	Diethylenetriamine 4,4'-Difluorobenzophenone	SML = 3 mg/kg SML = 0.05 mg/kg
15820	000343-92-0	4,4 -Diffuorobenzophenone	SWL = 0.03 mg/kg
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML = 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'-diisocyanatobi- phenyl	QM(T) = 1 mg/kg in FP (expressed as NCO)
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'-diisocya- nate	QM(T) = 1 mg/kg in FP (expressed as NCO)
16630	000101-68-8	Diphenylmethane 4,4'-diisocya- nate	QM(T) = 1 mg/kg in FP (expressed as NCO)
16660	000110-98-5	Dipropyleneglycol	
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	C) (T 12 [#]
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1 000151-56-4	Ethyleneglycol	SML(T) = 30 mg/kg alone with diethyleneglycol
17005	000131-36-4	Ethyleneimine	$\blacktriangleright \underline{M1} SML = ND (DL)$ $= \overline{0,01} mg/kg) \blacktriangleleft$

▼ <u>C1</u>			1	
	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
	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	SML = 0.01 mg/kg
▼ <u>C1</u>	17170	061788-47-4	Fatty acids, coco	
	17200	068308-53-2	Fatty acids, soya	
	17230	061790-12-3	Fatty acids, tall oil	
	17260	000050-00-0	Formaldehyde	SML = 15 mg/kg
	17290	000110-17-8	Fumaric acid	
	17530	000050-99-7	Glucose	
	18010	000110-94-1	Glutaric acid	
▼ <u>M1</u>	18070	000108-55-4	Glutaric anhydride	
▼ <u>C1</u>	18100	000056-81-5	Glycerol	
▼ <u>M1</u>	18250	000115-28-6	Hexachloroendomethylenetetrahy- drophthalic acid	SML = ND (DL = 0.01 mg/kg)
	18280	000115-27-5	Hexachloroendomethylenetetrahy- drophthalic anhydride	SML = ND (DL = 0.01 mg/kg)
▼ <u>C1</u>	18310	036653-82-4	1-Hexadecanol	
▼ <u>M1</u>	18430	000116-15-4	Hexafluoropropylene	SML = ND (LD) $= 0.01 mg/kg)$
▼ <u>C1</u>				
	18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/kg
	18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	18670	000100-97-0	Hexamethylenetetramine	► <u>M1</u> SML (T) = 15 mg/kg (expressed as formalde- hyde) \blacktriangleleft
		000123-31-9	Hydroquinone	See '1,4-Dihydroxybenzene'
	18880	000099-96-7	P-Hydroxybenzoic acid	
	19000	000115-11-7	Isobutene	
▼ <u>M2</u>	19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg
▼ <u>M3</u>	19270	000097-65-4	Itaconic acid	
▼ <u>M4</u> ▼ <u>M1</u>	19460	000050-21-5	Lactic acid	
▼ <u>M4</u>	19470	000143-07-7	Lauric acid	
▼ <u>C1</u>	19480	002146-71-6	Lauric acid, vinyl ester	
·	19510	011132-73-3	Lignocellulose	
	19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg
	19960	000108-31-6	Maleic anhydride Melamine	SML(T) = 30 mg/kg (expressed as maleic acid) See '2,4,6-Triamino-1,3,5-tria-
	20020	000108-78-1	Methacrylic acid	zine'
▼M2	20020	000079 -11 -T		
	20080	002495-37-6	Methacrylic acid, benzyl ester	

	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
	(1)	(2)	(5)	(ד)
▼ <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	
	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	(orefunce included)
▼M1				
	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>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-Napthalene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
	22450	009004-70-0	Nitrocellulose	
	22480	000143-08-8	1-Nonanol	
	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	
	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>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	

▼C1				
	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
	23470	000080-56-8	alpha-Pinene	
	23500	000127-91-3	beta-Pinene	
	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	
	23800	000071-23-8	1-Propanol	
	23830	000067-63-0	2-Propanol	
	23860	000123-38-6	Propionaldehyde	
	23890	000079-09-4	Propionic acid	
	23950	000123-62-6	Propionic anhydride	
	23980	000115-07-1	Propylene	
	24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP
	24010	000120-80-9	Pyrocatechol	See '1,2-Dihydroxybenzene'
▼M2		000120-80-9	1 ylocatechol	See 1,2-Dillydroxybelizene
▼ <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	
	24070			See (1.2 Dihadaan harmona)
	24100	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	
	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, monoso- dium salt	► $\underline{M3}$ SML = 5 mg/kg <
▼ <u>M2</u>	24888	003965-55-7	5-Sulphoisophthalic acid, monoso- dium salt, dimethyl ester	SML = 0,05 mg/kg

	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
▼ <u>C1</u>	24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
▼ <u>M2</u>	24940	000100-20-9	Terephtalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as terephtalic acid)
▼ <u>C1</u>	24970	000120-61-6	Terephthalic acid, dimethyl ester	
	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	SML = 6 mg/kg
	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>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> ▼ <u>C1</u>	26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg

SECTION B

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY CONTINUE TO BE USED PENDING A DECISION ON INCLU-SION 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	

	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
▼ <u>M1</u>	11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	
	11245	002156-97-0	Acrylic acid, dodecyl ester	
▼ <u>C1</u>	11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
	11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	
▼ <u>M1</u>	12265	004074-90-2	Adipic acid, divinyl ester	
▼ <u>C1</u>	12910	001732-10-1	Azelaic acid, dimethyl ester	
	12910	001732-10-1	1,2,4-Benzenetricarboxylic acid	See 'Trimellitic acid'
	13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	
		000091-76-9	Benzoguanamine	See '2,4-Diamino-6-phenyl- 1,3,5-triazine'
	13570	000080-09-1	Bisphenol S	See '4,4-Dihydroxydiphenyl sulphone'
	13720	000110-63-4	1,4-Butanediol	
	13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	QM(T) = 5 mg/kg in FP (expressed as epoxy)
	13810	000505-65-7	1,4-Butanediol formal	
▼ <u>M1</u>	13932	000598-32-3	3-Buten-2-ol	
▼ <u>C1</u>	14020	000098-54-4	4-tert-Butylphenol	
	14260	000502-44-3	Caprolactone	
	14470	000115-28-6	Chlorendic acid	See 'Hexachloroendo-methyle- netetrahydrophthalic acid'
	14800	003724-65-0	Crotonic acid	
	15130	000872-05-9	1-Decene	
	15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-tria- zine	
	15370	003236-53-1	1,6-Diamino-2,2,4-trimethyl- hexane	
	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'-diaminodicy- clohexylmethane	
	16360	000576-26-1	2,6-Dimethylphenol	
	16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	
	16450	000646-06-0	1,3-Dioxolane	
	16540	000102-09-0	Diphenyl carbonate	
W M 1	16690	001321-74-0	Divinylbenzene	
▼ <u>M1</u>	16697	000693-23-2	Dodecanedioic acid	
▼ <u>C1</u>	17110	016219-75-3	5-Ethylidenebi- cyclo[2.2.1]hept-2-ene	
	18220	068564-88-5	N-Heptylaminoundecanoic acid	
	18370	000592-45-0	1,4-Hexadiene	
▼ <u>M1</u>	18441	000085-42-7	Hexahydrophthalic anhydride	

	PM/REF No	CAS No	Name	Restrictions
•	(1)	(2)	(3)	(4)
	(1)	(2)	(3)	(ד)
▼ <u>C1</u>	18700	000629-11-8	1,6-Hexanediol	
	18820	000592-41-6	1-Hexene	
	19060	000109-53-5	Isobutyl vinyl ether	
	19150	000121-91-5	Isophthalic acid	
	19180	000099-63-8	Isophthalic acid dichloride	
	19240	000078-79-5	Isoprene	See '2-Methyl-1,3-butadiene'
▼ <u>M1</u>	19490	000947-04-6	Laurolactam	
▼ <u>C1</u>	19570	000999-21-3	Maleic acid, diallyl ester	
	19600	000105-76-0	Maleic acid, dibutyl ester	
	19990	000079-39-0	Methacrylamide	
	20050	000096-05-9	Methacrylic acid, allyl ester	
	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	
	20530	002867-47-2	Methacrylic acid, 2-(dimethyla- mino)ethyl ester	
	20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QM(T) = 5 mg/kg in FP (expressed as epoxy)
	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	
	21730	000563-45-1	3-Methyl-1-butene	
	21820	000505-65-7	1,4-(Methylenedioxy)butane	See '1,4-Butanediol formal'
	21970	000923-02-4	N-Methylolmethacrylamide	
	22210	000098-83-9	alpha-Methylstyrene	
	22360	001141-38-4	2,6-Naphtalenedicarboxylic acid	
		000126-30-7	Neopentylglycol	See '2,2-Dimethyl-1,3-propane- diol'
▼ <u>M1</u>				
	22428	051000-52-3	Neodecanoic, vinyl ester	
▼ <u>C1</u>	22540	000498-66-8	Norbornene	See 'Bicyclo[2.2.1]hept-2-ene'
	22720	000140-66-9	4-tert-Octylphenol	
	22900	000109-67-1	1-Pentene	
▼ <u>M1</u>	22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	
▼ <u>C1</u>	23140	000092-69-3	Phthalic acids	See 'Iso- or <i>o</i> -phthalic acid'

▼ C1				
	PM/REF No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
	23770	000504-63-2	1,3-Propanediol	
	23920	000105-38-4	Propionic acid, vinyl ester	
	24370	000106-79-6	Sebacic acid, dimethyl ester	
	24760	026914-43-2	Styrenesulphonic acid	
▼ <u>M1</u>	25380		Trialkyl (C5-C15) acetic acid, vinyl ester (= vinyl versatate)	
▼ <u>C1</u>	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 triacry- late	
	25840	003290-92-4	1,1,1-Trimethylolpropane trime- thacrylate	
	25900	000110-88-3	Trioxane	
		000102-71-6	Tris(2-hydroxyethyl)amine	See 'Triethanolamine'
	26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 5 mg/kg in FP
	26230	000088-12-0	Vinylpyrrolidone	
	26290	000622-97-9	<i>p</i> -Vinyltoluene	See 'p-Methylstyrene'
	26320	000105-67-9	m-Xylenol	See '2,4-Dimethylphenol'
		000526-75-0	o-Xylenol	See '2,3-Dimethylphenol'
▼ <u>M1</u>		000095-87-4	<i>p</i> -Xylenol	See '2,5-Dimethylphenol'
▼ <u>M2</u>				
▼ <u>M3</u>				
▼ <u>M4</u>				

▼C1

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,
 - column 4 (Restrictions). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the 'residual', substance in the material or article (QM),
 - any other restriction specifically mentioned.
- 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.

Incomplete list of additives

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
30000	000064-19-7	Acetic acid	
30045	000123-86-4	Acetic acid, butyl ester	
30140	000141-78-6	Acetic acid, ethyl ester	
30280	000108-24-7	Acetic anhydride	
30295	000067-64-1	Acetone	

<u>M3</u>			1	
	PM/Ref No	CAS No	Name	Restrictions
	(1)	(2)	(3)	(4)
-	30370	_	Acetylacetic acid, salts	
	30400	_	Acetylated glycerides	
	30960	_	Acids aliphatic monocarboxylic (C_6-C_{22}) esters with polyglycerol	
	31328	_	Acids, fatty, from animal or vegetable food fats and oils	
	31730	000124-04-9	Adipic acid	
	33120	_	Alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{24})	
MA	33350	009005-32-7	Alginic acid	
<u>M4</u>	34281	_	Alkyl(C_8 - C_{22}) sulphoric acids, linear, primary, with an even number of carbon atoms	
	34475	_	Aluminium calcium hydroxide phosphite, hydrate	
<u>M3</u>	34480	_	Aluminium fibers, flakes and powders	
	34560	021645-51-2	Aluminium hydroxide	
	34690	011097-59-9	Aluminium magnesium carbonate hydroxide	
	34720	001344-28-1	Aluminium oxide	
	35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	
	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	
	36880	008012-89-3	Beeswax	
	36960	003061-75-4	Behenamide	
	37040	000112-85-6	Behenic acid	
	37280	001302-78-9	Bentonite	
	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	
	38950	079072-96-1	Bis (4-ethylbenzylidene) sorbitol	
	39890	087826-41-3 069158-41-4 054686-97-4	Bis (methylbenzylidene) sorbitol	
	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 037293-22-4	Calcium sulphoaluminate	

<u>M3</u>		1	· · · · · · · · · · · · · · · · · · ·	
_	PM/Ref No	CAS No	Name	Restrictions
_	(1)	(2)	(3)	(4)
	41760	008006-44-8	Candelilla wax	
	41960	000124-07-2	Caprylic acid	
	42160	000124-38-9	Carbon dioxide	
	42500		Carbonic acid, salts	
	42640	009000-11-7	Carboxymethylcellulose	
	42720	008015-86-9	Carnauba wax	
	42800	009000-71-9	Casein	
	42960	064147-40-6	Castor oil, dehydrated	
	43200		Castor oil, mono- and diglycerides	
	43280	009004-34-6	Cellulose	
	43300	009004-36-8	Cellulose acetate butyrate	
	43360	068442-85-3	Cellulose, regenerated	
	43440	008001-75-0	Ceresin	
	44160	000077-92-9	Citric acid	
	44640	000077-93-0	Citric acid, triethyl ester	
	45280	_	Cotton fibers	
	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>14</u>	46380	068855-54-9	Diatomaceous earth, soda ash flux-calcined	
13	46480	032647-67-9	Dibenzylidene sorbitol	
	46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxyben- zoic acid, 2,4-di-tert-butylphenyl ester	
	46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxyben- zoic acid, hexadecyl ester	
	46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxyben- zylphosphonic acid, dioctadecyl ester	
	47440	000461-58-5	Dicyanodiamide	
	49540	000067-68-5	Dimethyl sulphoxide	
	51200	000126-58-9	Dipentaerythritol	
	51760	025265-71-8 000110-98-5	Dipropyleneglycol	
	52640	016389-88-1	Dolomite	
<u>14</u>	52720	000112-84-5	Erucamide	
<u>13</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>M3</u>				
-	PM/Ref No	CAS No	Name	Restrictions
-	(1)	(2)	(3)	(4)
	54005	005136-44-7	Ethylene-N-palmitamide-N' -stearamide	
	54260	009004-58-4	Ethylhydroxyethylcellulose	
	54270	—	Ethylhydroxymethylcellulose	
	54280		Ethylhydroxypropylcellulose	
	54450		Fats and oils, from animal or vegetable food sources	
	54480		Fats and oils, hydrogenated, from animal or vegetable food sources	
	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	
		099880-64-5	-	
	56020	099880-64-5	Glycerol dibehenate	
′ M4	56360		Glycerol, esters with acetic acid	
	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})	
<u>M3</u>	56487	_	Glycerol, esters with butyric acid	
	56490		Glycerol, esters with erucic acid	
	56495	—	Glycerol, esters with 12-hydroxys- tearic acid	
	56500		Glycerol, esters with lauric acid	
	56510		Glycerol, esters with linoleic acid	
	56520		Glycerol, esters with myristic acid	
	56540		Glycerol, esters with oleic acid	
	56550		Glycerol, esters with palmitic acid	
	56565	—	Glycerol, esters with nonanoic acid	
	56570		Glycerol, esters with propionic acid	
	56580		Glycerol, esters with ricinoleic acid	
	56585		Glycerol, esters with stearic acid	
	56610	030233-64-8	Glycerol monobehenate	
	56720	026402-23-3	Glycerol monohexanoate	
	56800	030899-62-8	Glycerol monolaurate diacetate	
	56880	026402-26-6	Glycerol monooctanoate	
	57040	_	Glycerol monooleate, ester with ascorbic acid	
	57120		Glycerol monooleate, ester with citric acid	
	57200	-	Glycerol monopalmitate, ester with ascorbic acid	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
57280		Glycerol monopalmitate, ester with citric acid	
57600	_	Glycerol monostearate, ester with ascorbic acid	
57680	—	Glycerol monostearate, ester with citric acid	
57920	000620-67-7	Glycerol triheptanoate	
58300		Glycine, salts	
58320	007782-42-5	Graphite	
58400	009000-30-0	Guar gum	
58480	009000-01-5	Gum arabic	
58720	000111-14-8	Heptanoic acid	
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
60030	012072-90-1	Hydromagnesite	
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	
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	
65020	006915-15-7	Malic acid	
65040	000141-82-2	Malonic acid	
65520	000087-78-5	Mannitol	

M 3				
	PM/Ref No	CAS No	Name	Restrictions
-	(1)	(2)	(3)	(4)
-	66200	037206-01-2	Methylcarboxymethylcellulose	
	66240	009004-67-5	Methylcellulose	
	66640	009004-59-5	Methylethylcellulose	
	66695	—	Methylhydroxymethylcellulose	
	66700	009004-65-3	Methylhydroxypropylcellulose	
	67120	012001-26-2	Mica	
	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	068187-64-4	Nepheline syenite	
<u>M4</u>	68960	000301-02-0	Oleamide	
M 3	00700	000301-02-0		
1115	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-hydroxy- phenyl)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	
	71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di- tert-butyl-4-hydroxy- phenyl)propionate]	
	71720	000109-66-0	Pentane	
	72640	007664-38-2	Phosphoric acid	
	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	
	76720	009016-00-6 063148-62-9	Polydimethylsiloxane	
	76960	025322-68-3	Polyethyleneglycol	
	77600	061788-85-0	Polyethyleneglycol ester of hydro- genated castor oil	
	77702		Polyethyleneglycol esters of aliphatic monocarboxylic acids (C_6-C_{22}) , and their ammonium and sodium sulphates	
	79040	009005-64-5	Polyethyleneglycol sorbitan mono- laureate	
	79120	009005-65-6	Polyethyleneglycol sorbitan mono- oleate	
	79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
	79280	009005-67-8	Polyethyleneglycol sorbitan mono- stearate	

▼<u>M4</u>

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
79360	009005-70-3	Polyethyleneglycol sorbitan trio- leate	
79440	009005-71-4	Polyethyleneglycol sorbitan tris- tearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	_	Polyoxyalkyl(C_2 - C_4)dime- thylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
80800	025322-69-4	Polypropyleneglycol	
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	
81840	000057-55-6	1,2-Propanediol	
81882	000067-63-0	2-Propanol	
82000	000079-09-4	Propionic acid	
82080	009005-37-2	1,2-Propyleneglycol alginate	
82240	022788-19-8	1,2-Propyleneglycol dilaurate	
82400	000105-62-4	1,2-Propyleneglycol dioleate	
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	
82720	006182-11-2	1,2-Propyleneglycol distearate	
82800	027194-74-7	1,2-Propyleneglycol monolaurate	
82960	001330-80-9	1,2-Propyleneglycol monooleate	
83120	029013-28-3	1,2-Propyleneglycol monopalmi- tate	
83300	001323-39-3	1,2-Propyleneglycol monostearate	
83320		Propylhydroxyethylcellulose	
83325		Propylhydroxymethylcellulose	
83330		Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
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	
85600	_	Silicates, natural	
85980	_	Silicic acid, salts	
86000	_	Silicic acid, silylated	
86160	000409-21-2	Silicon carbide	
86240	007631-86-9	Silicon dioxide	
86560	007647-15-6	Sodium bromide	

▼<u>M4</u>

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
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	
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	
88800	009005-25-8	Starch, edible	
88880	068412-29-3	Starch, hydrolysed	
00000	000112 29 5	Staron, ny arony sea	
88960	000124-26-5	Stearamide	
89040	000057-11-4	Stearic acid	
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	
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	
93440	013463-67-7	Titanium dioxide	
93520	000059-02-9 010191-41-0	alpha-Tocopherol	
93680	009000-65-1	Tragacanth gum	
94320	000112-27-6	Triethyleneglycol	
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di- tert-butyl-4-hydroxy- benzyl)benzene	
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	