

SUBSIDIARY LEGISLATION 231.31

**MATERIALS AND ARTICLES IN CONTACT
WITH FOODSTUFFS REGULATIONS**

1st January, 1997

Legal Notice 4 of 1996.

1. The title of these Regulations is Materials and Articles in Contact with Foodstuffs Regulations. Title.

2. (1) These regulations shall apply to materials and articles which, in their finished state, are brought or are intended to be brought into contact with foodstuffs or with water which, in either case, are intended for human consumption. Scope.

(2) These regulations shall not apply to:

- (a) covering or coating substances, including the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs;
- (b) fixed public or private water supply equipment.

3. In these regulations, unless the context otherwise requires - Interpretation.

"ceramic articles" means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added; these articles are first shaped, the shape thus obtained being permanently fixed by firing and they may be glazed, enamelled and/or decorated;

"EEC" as used in these regulations and in the Schedules thereto means the European Economic Community;

"foodstuffs" has the same meaning as is attributed to "food" in article 2 of the Food, Drugs and Drinking Water Act;

Cap. 231.

"N-nitrosatable substances" means substances capable of being converted into N-nitrosamines;

"not detectable" means that the analyte should not be detected by a validated method of analysis which should detect it at the detection limit specified;

"plastics" means 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, and includes silicones and other similar macromolecular compounds to which other substances or matter may be added, but does not include:

- varnished or unvarnished regenerated cellulose film;
- elastomers and natural and synthetic rubber;
- paper and paperboard, whether modified or not by the

addition of plastics;

- surface coatings obtained from:
 - paraffin waxes, including synthetic paraffin waxes and/or micro-crystalline waxes; or
 - mixtures of such waxes with each other and/or with plastics;
- ion-exchange resins;

"regenerated cellulose film" means a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton and to which suitable substances may be added either in the mass or on the surface to meet technical requirements and which may be coated on one or both sides;

"validated method" means an analytical method which is proven to give precise and accurate results.

Manufacture of materials and articles.

4. Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could -

- (i) endanger human health;
- (ii) bring about an unacceptable change in the composition of the foodstuff or a deterioration in the organoleptic characteristics thereof.

Groups of materials and articles.

5. The groups of materials and articles listed in the First Schedule and, where appropriate, combinations of these materials and articles, shall be subject to the provisions of these regulations.

Materials and articles not already in contact with foodstuffs.

6. (1) Without prejudice to any exceptions provided for in these regulations, materials or articles intended to come into, but not already in contact with foodstuffs may not be sold or imported unless accompanied by a label or other indication bearing:

- (a) the words "for food use", or
 - a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon, or
 - a symbol as indicated in the Second Schedule
- (b) where appropriate, any special conditions to be observed when they are being used;
- (c) either the name or trade name and address or registered office,
 - or the registered trade mark
 of the manufacturer or processor, or of a seller established in Malta.

(2) At the retail stage to the ultimate consumer, particulars listed in sub-regulation (1) must be conspicuous, clearly legible and indelible and shall appear -

- (a) on the materials or articles or on their packaging; or
- (b) on labels affixed to the materials or articles or to their packaging; or

- (c) on a notice in the immediate vicinity of the materials and articles and clearly visible to the purchasers:

Provided that, in respect of those particulars referred to in sub-regulation (1)(c), the option in sub-regulation (2)(c) shall only apply if these particulars or a label bearing them, cannot, for technical reasons, be affixed to the said materials or articles.

(3) At the marketing stages other than the retail stage to the ultimate consumer the following provisions shall apply:

- (a) materials or articles must be accompanied by a written declaration attesting that they comply with the rules applicable to them, and
- (b) in addition, the particulars listed in sub-regulation (1) shall appear:
- (i) on the accompanying documents, and
 - (ii) on the labels or packaging, or
 - (iii) on the materials or articles themselves.

(4) The particulars listed in sub-regulation (1)(a) and the provision referred to in sub-regulation (3)(a) shall not be compulsory for materials or articles which by their nature are clearly intended to come into contact with foodstuffs.

(5) The particulars provided for in sub-regulation (1)(a) and (b) shall be confined to materials or articles which comply -

- (a) with the criteria laid down in regulation 4, and
- (b) with those provisions in these regulations relating to the specific group of materials or articles.

(6) The particulars required in this regulation shall be given in, at least, one of the official languages of Malta. This requirement does not however preclude the use of other languages in addition to the language or languages of Malta.

7. (1) Materials or articles prepared with vinyl chloride polymers or copolymers must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram in the final product.

Limits for vinyl
chloride monomer.

(2) Materials or articles referred to in sub-regulation (1) must not pass on to foodstuffs which are in or have been brought into contact with such materials or articles, any vinyl chloride in a quantity equal to or in excess of 0.01 mg per kilogram of the foodstuff.

(3) The methods of analysis for the determination of the vinyl chloride levels referred to in sub-regulations (1) and (2) shall be as laid down in the European Community Directives 80/766/EEC and 81/432/EEC respectively. The determination of vinyl chloride released by materials or articles to foodstuffs referred to in sub-regulation (2) shall preferably be determined in the foodstuffs themselves, except that, when such determination is shown to be impossible for technical reasons, determination by simulants for these particular foodstuffs is permitted.

Plastic materials
and articles.

8. (1) Materials or articles consisting exclusively of plastics, or 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, shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre (mg/dm^2) of surface area of material or article (overall migration limit):

Provided that, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff in the following cases:

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

(2) The provisions of this regulation shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

(3) (a) Only those monomers and other starting substances listed in Sections A and B of the Third Schedule may be used for the manufacture of plastic materials and articles subject to the restrictions specified therein:

Provided that the starting substances listed in Section B of the said Schedule shall not be so used after the 1st January 1997.

(b) The quantities specified in column 4 of Sections A and B of the Third Schedule shall be determined by a validated method of analysis at the specified limit.

(4) An initial list of additives which may be used for the manufacture of plastic materials and articles is set out in the Fourth Schedule.

(5) The specific migration limits laid down in the list set out in the Third Schedule are expressed in milligrams per kilogram (mg/kg). Such limits are expressed in milligrams per square decimetre (mg/dm^2) in the following cases:

- articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 millilitres or more than 10 litres;
- 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 the Third Schedule

expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

(6) Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in European Community Directives 82/711/EEC, 85/572/EEC and 90/128/EEC.

(7) Verification of compliance with the specific migration limits laid down in the Third Schedule shall not be compulsory, if -

- it can be established that compliance with the overall migration limit laid down in sub-regulation (1) implies that the specific migration limits are not exceeded; or
- 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.

9. (1) The provisions of this regulation shall apply to regenerated cellulose film, which either - Regenerated cellulose film.

- constitutes a finished product in itself; or
- forms part of a finished product containing other materials,

and which is intended to come into contact with foodstuffs, or which, by virtue of its purpose, does come into such contact.

(2) The provisions of this regulation shall not apply to:

- regenerated cellulose film which on the side intended to come into contact with foodstuffs or which, by virtue of its purposes does come into such contact, has a coating exceeding 50mg/dm²;
- synthetic casings of regenerated cellulose.

(3) Only those substances or groups of substances listed in the Fifth Schedule may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein:

Provided that, substances other than those listed in the Fifth Schedule may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.

(4) Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.

10. (1) The quantities of lead and cadmium transferred from ceramic articles shall not exceed the limits laid down in sub-regulation (3). Such quantities shall be determined by the methods laid down in European Community Directive 84/500/EEC. Ceramics.

(2) Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (in mg/dm² or mg/l) shall be that which applies to the vessel alone. The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions. The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the

vessel alone.

(3) A ceramic article shall be recognised as satisfying the requirements of this regulation if the quantities of lead and/or cadmium extracted as described in the preceding sub-regulations do not exceed the following limits:

- Category 1: This category comprises:
 - (i) articles which cannot be filled, and
 - (ii) articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm:
 - 0.8 mg/dm² for lead
 - 0.07 mg/dm² for cadmium
- Category 2: All other articles which can be filled:
 - 4.0 mg/l for lead
 - 0.3 mg/l for cadmium
- Category 3: This category comprises:
 - (i) cooking ware, and
 - (ii) packaging and storage vessels having a capacity of more than three litres.
 - 1.5 mg/l for lead
 - 0.1 mg/l for cadmium

Provided that, if a ceramic article exceeds the above quantities by less than 50%, that article shall nevertheless be recognised as satisfying the requirements of this regulation, if, at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out as described in the preceding sub-regulations, and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50%.

Teats and soothers.

11. Teats and soothers made of elastomer or rubber must not pass on to the release-test liquid (saliva test solution) under the conditions specified in European Community Directive 93/11/EEC any N-nitrosamine and N-nitrosatable substance detectable by a validated method which can detect the following quantities:

- 0.01 mg in total of N-nitrosamines released per kilogram of the parts of teat or soother made of elastomer or rubber;
- 0.1 mg in total of N-nitrosatable substances per kilogram of the parts of teat or soother made of elastomer or rubber.

Compliance with these regulations.

12. (1) No person may import, sell, keep for sale, or supply by way of compensation or otherwise, any material or article or any foodstuff which has been or is in contact with such material or article in either case unless the material or article is in compliance with the provisions of these regulations.

(2) No person may manufacture any material or article or put, wrap or pack any foodstuff in such material or article which in either case does not comply with the provisions of sub-regulation (1).

FIRST SCHEDULE

(Regulation 5)

List of groups of materials and articles

Plastics, including varnish and coatings

Regenerated cellulose

Elastomers and rubber

Paper and board

Ceramics

Glass

Metals and alloys

Wood, including cork

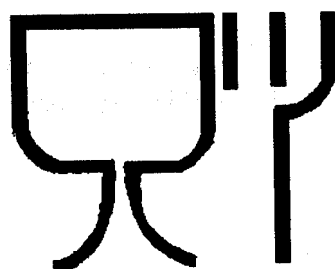
Textile products

Paraffin waxes and micro-crystalline waxes

SECOND SCHEDULE

(Regulation 6)

Symbol that may accompany materials and articles intended to come into contact with foodstuffs



THIRD SCHEDULE

(Regulation 8)

List of Monomers and other Starting Substances which may be used in the manufacture of Plastic Materials and Articles

General introduction

1. This Schedule 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 substances indicated under (a), (b) and (c) shall comply with the requirements stated in regulation 4.

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 of the list,
- column 2 (CAS No): the CAS (Chemical Abstracts Service) Registry number,
- column 3 (Name): the chemical name,
- column 4 (Restrictions).

These restrictions in column 4 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 (the European Inventory of Existing Commercial Chemical Substances) and the CAS Registry, the CAS number in the CAS Registry shall apply.

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

DL = detection limit of the method of analysis;

FP = finished material or article;

NCO = isocyanate moiety;

ND = not detectable;

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;

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

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

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	
10210	000074-86-2	Acetylene	
10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
10690	000079-10-7	Acrylic acid	
10750	002495-35-4	Acrylic acid, benzyl ester	
10780	000141-32-2	Acrylic acid, n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid, tert-butyl ester	
11470	000140-88-5	Acrylic acid, ethyl ester	
	000818-61-1	Acrylic acid, hydroxyethyl ester	See 'Acrylic acid, monoester with ethyleneglycol'
11590	000106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
11890	002499-59-4	Acrylic acid, n-octyl ester	
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = not detectable (DL = 0,020 mg/kg analytical tolerance included)
12130	000124-04-9	Adipic acid	
12280	002035-75-8	Adipic anhydride	
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6 mg/kg
12788	002432-99-7	11-Aminoundecanoic acid	SML = 5 mg/kg
12789	007664-41-7	Ammonia	
12820	000123-99-9	Azelaic acid	
12970	004196-95-6	Azelaic anhydride	
13000	001477-55-0	1,3-Benzenedimethanamine	SML = 0,05 mg/kg
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 in 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'

13530	038103-06-9	2,2-Bis(4-hydroxyphenyl) propane bis(phthalic anhydride)	SML = 0,05 mg/kg
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'
13614	038103-06-9	Bisphenol A bis(phthalic anhydride)	See 13530
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	
14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
14411	008001-79-4	Castor oil	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
	000106-89-8	1-Chloro-2,3-epoxypropane	See 'Epichlorohydrin'
14680	000077-92-9	Citric Acid	
14710	000108-39-4	m-Cresol	
14740	000095-48-7	o-Cresol	
14770	000106-44-5	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'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg alone or with ethyleneglycol
15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
15820	000345-92-6	4,4'-Difluorobenzophenone	SML = 0.05 mg/kg
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2.4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML = 6 mg/kg
16000	000092-88-6	4,4'-Dihydroxybiphenyl	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)
16480	000126-58-9	Dipentacrythritol	
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	Dipropylene glycol	
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg alone or with diethyleneglycol
17005	000151-56-4	Ethyleneimine	SML = ND (DL = 0.01 mg/kg)
17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg
17160	000097-53-0	Eugenol	SML = 0.01 mg/kg
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	
18070	000108-55-4	Glutaric anhydride	
18100	000056-81-5	Glycerol	
18250	000115-28-6	Hexachloroendomethylenetetra- hydrophthalic acid	SML = ND (DL = 0.01 mg/kg)
18280	000115-27-5	Hexachloroendomethylenetetra- hydrophthalic anhydride	SML = ND (DL = 0.01 mg/kg)
18310	036653-82-4	1-Hexadecanol	
18430	000116-15-4	Hexafluoropropylene	SML = ND (DL = 0.01 mg/kg)
18460	000124-09-4	Hexamethylenediamine	SML = 2.4 mg/kg
18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
18670	000100-97-0	Hexamethylenetetramine	SML (T) = 15 mg/kg (expressed as formaldehyde)
18880	000123-31-9	Hydroquinone	See '1,4-Dihydroxybenzene'
19000	000099-96-7	p-Hydroxybenzoic acid	
19000	000115-11-7	Isobutene	
19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0.05 mg/kg

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
19270	000097-65-4	Itaconic acid	SML(T) = 30 mg/kg SML(T) = 30 mg/kg (expressed as maleic acid)
19470	000143-07-7	Lauric acid	
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	
19960	000108-31-6	Maleic anhydride	
	000108-78-1	Melamine	See '2,4,6-Triamino-1,3,5-triazine'
20020	000079-41-4	Methacrylic acid	SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
20080	002495-37-6	Methacrylic acid, benzyl ester	
20110	000097-88-1	Methacrylic acid, butyl ester	
20140	002998-18-7	Methacrylic acid, sec-butyl ester	
20170	000585-07-9	Methacrylic acid, tert-butyl ester	
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	
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	
21280	002177-70-0	Methacrylic acid, phenyl ester	
21340	002210-28-8	Methacrylic acid, propyl ester	
21460	000760-93-0	Methacrylic anhydride	
21490	000126-98-7	Methacrylonitrile	
21550	000067-56-1	Methanol	SML = ND (DL = 0,01 mg/kg)
21940	000924-42-5	N-Methylolacrylamide	
22150	000691-37-2	4-Methyl-1-pentene	
22350	000544-63-8	Myristic acid	SML = 0,02 mg/kg
22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	
22420	003173-72-6	1,5-Naphthalene diisocyanate	SML = 0,05 mg/kg
22450	009004-70-0	Nitrocellulose	M(T) = 1 mg/kg in FP (expressed as NCO)
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	SML = 15 mg/kg
22660	000111-66-0	1-Octene	
22763	000112-80-1	Oleic acid	
22780	000057-10-3	Palmitic acid	
22840	000115-77-5	Pentacrythritol	
22870	000071-41-0	1-Pentanol	
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	
	000075-44-5	Phosgene	
23170	007664-38-2	Phosphoric acid	
		Phthalic acid	See 'Terephthalic acid'
23200	000088-99-3	o-Phthalic acid	
23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg)
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	
23500	000127-91-3	beta-Pinene	
23590	025322-68-3	Polyethyleneglycol	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
23650	025322-69-4	Polypropyleneglycol (Molecular weight greater than 400)	
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
	000120-80-9	Pyrocatechol	See '1,2-Dihydroxybenzene'
24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as pyromellitic acid)
24070	073138-82-6	Resin acids and rosin acids	
	000108-46-3	Resorcinol	See '1,3-Dihydroxybenzene'
24100	008050-09-7	Rosin	
24130	008050-09-7	Rosin gum	see 'Rosin'
24160	008052-10-6	Rosin tall oil	
24190	009014-63-5	Rosin wood	
24250	009006-04-6	Rubber, natural	
24270	000069-72-7	Salicylic acid	
24280	000111-20-6	Sebacic acid	
24430	002561-88-8	Sebacic anhydride	
24475	001313-82-2	Sodium sulphide	
24490	000050-70-4	Sorbitol	
24520	008001-22-7	Soybean oil	
24540	009005-25-8	Starch, edible	
24550	000057-11-4	Stearic acid	
24610	000100-42-5	Styrene	
24820	000110-15-6	Succinic acid	
24850	000108-30-5	Succinic anhydride	
24880	000057-50-1	Sucrose	
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 5 mg/kg
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg
24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
24940	000100-20-9	Terephthalic acid dichloride	SML (T) = 7,5 mg/kg (expressed as terephthalic acid)
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg
25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
25180	000102-60-3	N,N,N',N'-Tetrakis (2-hydroxypropyl)-ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg 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)

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
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
25910	024800-44-0	Tripropyleneglycol	
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)
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 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'
10160	002206-94-2	alpha-Acetoxystyrene	
10162	010521-96-7	beta-Acetoxystyrene	
10480		Acids, aliphatic, monocarboxylic, saturated (C2-C24)	
10510		Acids, aliphatic, monocarboxylic, unsaturated (C3-C24)	
10599/70		Acids, fatty, unsaturated (C18)	
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	
10930	003066-71-5	Acrylic acid, cyclohexyl ester	
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	
11050	001070-70-8	Acrylic acid, diester with 1,4-butanediol	
11180	017831-71-9	Acrylic acid, diester with tetraethylene-glycol	
11195	068901-05-3	Acrylic acid, diester with tripropylene-glycol	
11245	002156-97-0	Acrylic acid, dodecyl ester	
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
11520	002918-23-2	Acrylic acid, 2-hydroxyisopropyl ester (= acrylic acid, 2-hydroxy-1-methylethyl ester)	
11530	000999-61-1	Acrylic acid 2-hydroxypropyl ester	
11560	005888-33-5	Acrylic acid, isobornyl ester	
11620	001330-61-6	Acrylic acid, isodecyl ester	
11650	029590-42-9	Acrylic acid, isooctyl ester	
11695	003121-61-7	Acrylic acid, 2-methoxyethyl ester	
11740	010095-13-3	Acrylic acid, monoester with 1,3-butanediol	
11770	002478-10-6	Acrylic acid, monoester with 1,4-butanediol	
11800	013533-05-6	Acrylic acid, monoester with diethyleneglycol	
12010	040074-09-7	Acrylic acid, 2-sulphoethyl ester	
12040	039121-78-3	Acrylic acid, sulphopropyl ester	
12055	094160-26-6	Acrylic acid, triester with glycerol	
		tris (2-hydroxypropyl) ether	
12062	075577-70-7	Acrylic acid, triester with 1,1,1-trimethylol-propane tris (2-hydroxyethyl) ether	
12160	002998-04-1	Adipic acid, diallyl ester	
12190	000105-97-5	Adipic acid, didecyl ester	
12220	027178-16-1	Adipic acid, diisodecyl ester	
12250	000123-79-5	Adipic acid, dioctyl ester	
12265	004074-90-2	Adipic acid, divinyl ester	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
12370		Alcohols, aliphatic, monohydric, saturated, linear, secondary or tertiary (C4-C22)	
12610	000107-18-6	Allyl alcohol	
12700	000150-13-0	p-Aminobenzoic acid	
12790	000080-46-6	p-tert-Amylphenol	
12850	029602-44-6	Azelaic acid, bis (2-hydroxyethyl) ester	
12910	001732-10-1	Azelaic acid, dimethyl ester	
	000528-44-9	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'
13328	000104-38-1	Bis(2-hydroxyethyl) ether of hydroquinone	
13660	000584-03-2	1,2-Butanediol	
13720	000110-63-4	1,4-Butanediol	
13750	000513-85-9	2,3-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	
13932	000598-32-3	3-Buten-2-ol	
13960	001852-16-0	N-(Butoxymethyl) acrylamide	
14020	000098-54-4	4-tert-Butylphenol	
14260	000502-44-3	Caprolactone	
	000115-28-6	Chlorendic acid	See 'Hexachloroendomethylene-tetrahydrophthalic acid'
14800	003724-65-0	Crotonic acid	
15020	002182-05-0	Cyclohexyl vinyl ether	
15130	000872-05-9	1-Decene	
15280	000542-02-9	2,4-Diamino-6-methyl-1,3,5-triazine	
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	
15340	000109-76-2	1,3-Diaminopropane	
15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	
15490	002215-89-6	4,4'-Dicarboxydiphenyl ether	
15580	001653-19-6	2,3-Dichloro-1,3-butadiene	
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	
16270	000526-75-0	2,3-Dimethylphenol	
16300	000105-67-9	2,4-Dimethylphenol	
16330	000095-87-4	2,5-Dimethylphenol	
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	
16690	001321-74-0	Divinylbenzene	
16697	000693-23-2	Dodecanedioic acid	
17040	000149-57-5	2-Ethylhexanoic acid	
17110	016219-75-3	5-Ethylidenebicyclo [2.2.1] hept-2-ene	
17350	000105-75-9	Fumaric acid, dibutyl ester	
18220	068564-88-5	N-Heptylamino undecanoic acid	
18370	000592-45-0	1,4-Hexadiene	
18400	000592-42-7	1,5-Hexadiene	
18441	000085-42-7	Hexahydrophthalic anhydride	
18700	000629-11-8	1,6-Hexanediol	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
18820	000592-41-6	1-Hexene	See '2-Methyl-1,3-butadiene'
18905	002628-17-3	4-Hydroxystyrene	
18970	000078-83-1	Isobutanol	
19030	016669-59-3	N-(Isobutoxymethyl) acrylamide	
19060	000109-53-5	Isobutyl vinyl ether	
19090	000078-84-2	Isobutyraldehyde	
19120	025339-17-7	Isodecanol	
19130	026896-18-4	Isononanoic acid	
19150	000121-91-5	Isophthalic acid	
19180	000099-63-8	Isophthalic acid dichloride	
	000078-79-5	Isoprene	
19490	000947-04-6	Lauro lactam	
19570	000999-21-3	Maleic acid, diallyl ester	
19600	000105-76-0	Maleic acid, dibutyl ester	
19936	007423-42-9	Maleic acid, mono (2-ethylhexyl) 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	
20470	025852-47-5	Methacrylic acid, diester with polyethyleneglycol	
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino) ethyl ester	QM(T) = 5 mg/kg in FP (expressed as epoxy)
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	
20740	039670-09-2	Methacrylic acid, ester with ethoxytriethyleneglycol	QM = 5 mg/kg in FP
20950	000923-26-2	Methacrylic acid, 2-hydroxypropyl ester	
21115	000081-67-40	Methacrylic acid, methylal ester	
21220	032360-05-7	Methacrylic acid, octadecyl ester	
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	
21640	000078-79-5	2-Methyl-1,3-butadiene	
21730	000563-45-1	3-Methyl-1-butene	
21760	000694-91-7	5-Methylenebicyclo[2.2.1]hept-2-ene	
	000505-65-7	1,4-(Methylenedioxy) butane	See '1,4-Butanediolformal'
21837	001116-90-1	4-Methyl-1,4-hexadiene	SML = ND (DL = 0.05 mg/kg)
21970	000923-02-4	N-Methylolmethacrylamide	
22210	000098-83-9	alpha-Methylstyrene	See '2,2-Dimethyl-1,3-propanediol'
22240	000622-97-9	p-Methylstyrene	
22270	000107-25-5	Methyl vinyl ether	
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	
	000126-30-7	Neopentylglycol	
22428	051000-52-3	Neodecanoic acid, vinyl ester	
22540	000104-40-5	4-Nonylphenol	
	000498-66-8	Norbornene	
22585	003710-30-3	1,7-Octadiene	
22720	000140-66-9	4-tert-Octylphenol	See 'Bicyclo[2.2.1]hept-2-ene'

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
22900	000109-67-1	1-Pentene	See 'Iso- or o-Phthalic acid'
22932	001187-93-5	Perfluoromethyl perfluorovinyl ether	
22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	
		Phthalic acids	
23530	025190-06-1	Poly(1,4-butyleneglycol) (molecular weight greater than 1000)	QM(T) = 5 mg/kg in FP QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
23770	000504-63-2	1,3-Propanediol	
23920	000105-38-4	Propionic acid, vinyl ester	
24370	000106-79-6	Sebacic acid, dimethyl ester	
24560	000111-63-7	Stearic acid, vinyl ester	
24760	026914-43-2	Styrenesulphonic acid	
25030	016646-44-9	Tetra (allyloxy) ethane	
25161	000085-43-8	1,2,3,6-Tetrahydrophthalic anhydride	
25300	000088-19-7	o-Toluenesulphonamide	
25380		Trialkyl (C5-C15) acetic acid, vinyl ester (= vinyl versatate)	
25390	000101-37-1	Triallyl cyanurate	
25450	026896-48-0	Tricyclodecanedimethanol	
25480	000102-71-6	Triethanolamine	
25540	000528-44-9	Trimellitic acid	
25550	000552-30-7	Trimellitic anhydride	
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	See 'p-Methylstyrene' QM = 5 mg/kg in FP See '2,4-Dimethylphenol' See '2,3-Dimethyl-phenol' See '2,5-Dimethyl-phenol'
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	
25900	000110-88-3	Trioxane	
	000102-71-6	Tris(2-hydroxyethyl)amine	
26170	003195-78-6	N-Vinyl-N-methylacetamide	
26230	000088-12-0	Vinylpyrrolidone	
26290	025013-15-4	Vinyltoluene	
	000622-97-9	p-Vinyltoluene	
26320	002768-02-7	Vinyltrimethoxysilane	
	000105-67-9	m-Xylenol	
	000526-75-0	o-Xylenol	
	000095-87-4	p-Xylenol	

FOURTH SCHEDULE

(Regulation 8(4))

Initial list of additives which may be used in the manufacture of plastic materials and articles

General introduction

1. This schedule 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 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) mixtures of the authorized substances.

The materials and articles which contain the substances indicated under (a) and (b) shall comply with the requirements stated in regulation 4.

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 of 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 (the European Inventory of Existing Commercial Chemical Substances) and the CAS Registry, the CAS number in the CAS Registry shall apply.

Initial 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	
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)	
33350	009005-32-7	Alginate acid	
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	Bis (methylbenzylidene) sorbitol	
	069158-41-4		
	054686-97-4		
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	
	037293-22-4		

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	
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-hydroxybenzylphospho- nic acid, dioctadecyl ester	
47440	000461-58-5	Dicyanodiamide	
49540	000067-68-5	Dimethyl sulphoxide	
51200	000126-58-9	Dipentaerythritol	
51760	025265-71-8	Dipropylene glycol	
	000110-98-5		
52640	016389-88-1	Dolomite	
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	
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	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
55040	000064-18-6	Formic acid	
55120	000110-17-8	Fumaric acid	
55190	029204-02-2	Gadoleic acid	
55440	009000-70-8	Gelatin	
55680	000110-94-1	Glutaric acid	
55920	000056-81-5	Glycerol	
56020	099880-64-5	Glycerol dibehenate	
56360	—	Glycerol, esters with acetic acid	
56487	—	Glycerol, esters with butyric acid	
56490	—	Glycerol, esters with erucic acid	
56495	—	Glycerol, esters with 12-hydroxystearic acid	
56500	—	Glycerol, esters with lauric acid	
56510	—	Glycerol, esters with linoleic acid	
56520	—	Glycerol, esters with myristic acid	
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
56565	—	Glycerol, esters with nonanoic acid	
56570	—	Glycerol, esters with propionic acid	
56580	—	Glycerol, esters with ricinoleic acid	
56585	—	Glycerol, esters with stearic acid	
56610	030233-64-8	Glycerol monobehenate	
56720	026402-23-3	Glycerol monohexanoate	
56800	030899-62-8	Glycerol monolaurate diacetate	
56880	026402-26-6	Glycerol monooctanoate	
57040	—	Glycerol monooleate, ester with ascorbic acid	
57120	—	Glycerol monooleate, ester with citric acid	
57200	—	Glycerol monopalmitate, ester with ascorbic acid	
57280	—	Glycerol monopalmitate, ester with citric acid	
57600	—	Glycerol monostearate, ester with ascorbic acid	
57680	—	Glycerol monostearate, ester with citric acid	
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	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
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	
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-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
68125	068187-64-4	Nepheline syenite	
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	
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	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
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	Polydimethylsiloxane	
	063148-62-9		
76960	025322-68-3	Polyethyleneglycol	
77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil	
77702	—	Polyethyleneglycol esters of aliphatic mono-carboxylic acids (C ₈ -C ₂₂), and their ammonium and sodium sulphates	
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl(C ₈ -C ₂₂)dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
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 monopalmitate	
83300	001323-39-3	1,2-Propyleneglycol monostearate	
83320	—	Propylhydroxyethylcellulose	
83325	—	Propylhydroxymethylcellulose	
83330	—	Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
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	

PM/Ref. No.	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
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	
86720	001310-73-2	Sodium hydroxide	
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	
87520	062568-11-0	Sorbitan monohehenate	
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	
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	alpha-Tocopherol	
	010191-41-0		
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-hydroxybenzyl)benzene	
95905	013983-17-0	Wollastonite	
95920	—	Wood flour and fibers, untreated	
95935	011138-66-2	Xanthan gum	
96190	020427-58-1	Zinc hydroxide	
96240	001314-13-2	Zinc oxide	
96320	001314-98-3	Zinc sulphide	

FIFTH SCHEDULE

(Regulation 9)

List of Substances authorized in the Manufacture of Regenerated Cellulose Film

The percentages in this Schedule, first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film. The substances used shall be of good technical quality as regards the purity criteria.

FIRST PART

Uncoated Regenerated Cellulose Film

Denominations	Restrictions
A. Regenerated cellulose	Not less than 72% (w/w)
B. Additives	
1. <i>Softeners</i>	Not more than 27% (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, i.e., which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200
— 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1% (w/w) in substance
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	
2. <i>Other additives</i>	Not more than 1% (w/w) in total
FIRST CLASS	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	

Denominations	Restrictions
<ul style="list-style-type: none"> — Ascorbic acid and its NH_4, Ca, Mg, K and Na salts — Benzoic acid and sodium benzoate — Formic acid and its NH_4, Ca, Mg, K and Na salts — Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH_4, Ca, Mg, K, Na, Al, Zn salts of these acids — Citric, d and l lactic, maleic, l-tartaric acids and their Na and K salts — Sorbic acid and its NH_4, Ca, Mg, K and Na salts — Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids — Natural edible starches and flours — Edible starches and flours modified by chemical treatment — Amylose — Calcium and magnesium carbonates and chlorides — Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids — Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive — Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive — Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol — Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium — Polyethylene oxide [= polyethyleneglycol] — Sodium propionate 	<p>Average molecular weight between 1200 and 4000</p>

Denominations	Restrictions
SECOND CLASS	The total quantity of the substances may not exceed 1 mg/dm ² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0,2 mg/dm ² (or a lower limit where one is specified) of the uncoated film
— Sodium alkyl (C ₈ to C ₁₈) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C ₈ to C ₁₈) sulphate	
— Sodium alkyl (C ₈ to C ₁₈) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0,05 mg/dm ² of the uncoated film
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
— 2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethyl-sulphate	Not more than 0,1 mg/dm ² of the uncoated film
THIRD CLASS — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm ² of the uncoated film
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0,5 mg/dm ² of the uncoated film Free melamine content not greater than 0,3 mg/dm ² of the uncoated film
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0,5 mg/dm ² of the uncoated film. Free melamine content not greater than 0,3 mg/dm ² of the uncoated film
— Cross-linked cationic polyalkyleneamines: (a) polyamide-epichlorhydrin resin based on diaminopropylmethyamine and epichlorhydrin (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine	In accordance with European Community directives, if applicable.

Denominations	Restrictions
<p>(c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia</p> <p>(d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine</p> <p>(e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine</p> <p>— Polyethyleneamines and polyethyleneimines</p> <p>— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or more of the following products:</p> <p>aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diamino-diethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite</p>	<p>Not more than 0,75 mg/dm² of the uncoated film</p> <p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film</p>
<p>FOURTH CLASS</p> <p>— Products resulting from the reaction of the amines of edible oils with polyethylene oxide</p> <p>— Monoethanolamine lauryl sulphate</p>	<p>The total quantity of substances may not exceed 0,01 mg/dm² of the uncoated film</p>

SECOND PART

Coated Regenerated Cellulose Film

Denominations	Restrictions
A. Regenerated cellulose	See first part of this Schedule
B. Additives	See first part of this Schedule
C. Coating	Not more than 50 mg of coating/dm ² of film on the side in contact with foodstuffs
1. <i>Polymers</i>	The total quantity of substances may not exceed 50 mg/dm ² of the coating on the side in contact with foodstuffs
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side in contact with foodstuffs; nitrogen content between 10,8% (w/w) and 12,2% (w/w) in the cellulose nitrate
— Polymers, copolymers and their mixtures made with the following monomers: vinyl acetals derived from saturated aldehydes (C ₁ to C ₄) vinyl acetate alkyl (C ₁ to C ₄) vinyl ethers acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters butadiene styrene methylstyrene vinylidene chloride acrylonitrile methacrylonitrile ethylene, propylene, 1- and 2-butylene vinyl chloride	In accordance with European Community directives, if applicable
	In accordance with regulation 7 of these regulations
2. <i>Resins</i>	The total quantity of substances may not exceed 12.5 mg/dm ² of the coating on the side in contact with foodstuffs and solely for the preparation of regenerated cellulose films with cellulose nitrate or vinyl chloride and vinyl acetate copolymer based coatings
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C ₂ to C ₆ polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/	

Denominations	Restrictions
<p>or 2,2 bis (4-hydroxyphenyl propane formaldehyde and esterified with methyl ethyl or C₂ to C₈ polyvalent alcohols or mixtures of these alcohols.</p> <p>— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride</p> <p>— Edible gelatine</p> <p>— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sabacic acids</p> <p>— Natural gum [= damar]</p> <p>— Poly-beta-pinene [= terpenic resins]</p> <p>— Urea-formaldehyde resins (see anchoring agents)</p> <p>3. <i>Plasticizers</i></p> <p>— Acetyl tributyl citrate</p> <p>— Acetyl tri(2-ethylhexyl) citrate</p> <p>— Di-isobutyl adipate</p> <p>— Di-n-butyl adipate</p> <p>— Di-n-hexyl azelate</p> <p>— Butylbenzylphthalate</p> <p>— Di-n-butyl phthalate</p> <p>— Dicyclohexyl phthalate</p> <p>— 2-ethylhexyl diphenyl phosphate</p> <p>— Glycerol monoacetate [= monoacetin]</p> <p>— Glycerol diacetate [= diacetin]</p> <p>— Glycerol triacetate [= triacetin]</p> <p>— Di-butyl sebacate</p> <p>— Di(2-ethylhexal) sebacate [= dioctyl-sebacate]</p> <p>— Di-n-butyl tartrate</p> <p>— Di-isobutyl tartrate</p>	<p>The total quantity of substances may not exceed 6 mg dm² of the coating on the side in contact with foodstuff</p> <p>Not more than 2,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 3,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 4,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 2,5 mg/dm² of the coating on the side in contact with foodstuffs</p>

Denominations	Restrictions
4. <i>Other additives</i>	The total quantity of substances may not exceed 6 mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs
4.1. <i>Additives listed in the first part</i>	Same restrictions as in the first part (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs)
4.2. <i>Specific coating additives:</i>	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C ₂₈ to C ₃₂) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	
— Carnauba wax	
— Beeswax	
— Esparto wax	
— Candelilla wax	
— Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side in contact with foodstuffs
— Epoxidized soya-bean oil (oxirane content 6 to 8%)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0,2 mg/dm ² of the coating on the side in contact with foodstuffs
— Aliphatic acids (C ₈ to C ₁₀) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [=butylated hydroxyanisole — BHA]	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs
— 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs
5. <i>Solvents</i>	The total quantity of substances may not exceed 0,6mg/dm ² of the coating on the side in contact with foodstuffs
— Butyl acetate	

Denominations	Restrictions
<ul style="list-style-type: none"> — Ethyl acetate — Isobutyl acetate — Isopropyl acetate — Propyl acetate — Acetone — 1-butanol — Ethanol — 2-butanol — 2-propanol — 1-propanol — Cyclohexane — Ethyleneglycol monobutyl ether — Ethyleneglycol monobutyl ether acetate — Ethyleneglycol monoethyl ether — Ethyleneglycol monoethyl ether acetate — Ethyleneglycol monomethyl ether — Ethyleneglycol monomethyl ether acetate — Methyl ethyl ketone — Methyl isobutyl ketone — Tetrahydrofuran — Toluene 	<p>Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs</p>