MERCOSUR/GMC/RES. No. 40/15

MERCOSUR TECHNICAL REGULATION ON CELLULOSIC MATERIALS, PACKAGING AND EQUIPMENT INTENDED TO COME INTO CONTACT WITH FOOD

(REPEAL OF RESOLUTIONS GMC No 19/94, 12/95, 35/97, 56/97, 52/99 and 20/00)

HAVING REGARD TO: The Treaty of Asuncion, the Protocol of Ouro Preto and Resolutions No 19/94, 12/95, 35/97, 56/97, 38/98, 52/99, 20/00 and 56/02 of the Common Market Group.

WHEREAS:

That the harmonization of the Technical Regulations tends to eliminate the barriers to trade generated by the different national regulations in force, in compliance with the provisions of the Treaty of Asunción.

That the States Parties, due to the progress made in this area, considered it necessary to update the MERCOSUR Technical Regulations on Cellulosic Packaging and Equipment in Contact with Foods (GMC Resolutions No. 19/94, 12/95, 35/97, 56/97, 52/99 and 20/00).

THE COMMON MARKET GROUP
RESOLVES:

Art. 1 - To approve the "MERCOSUR Technical Regulation on Cellulosic Materials, Containers and Equipment destined to come in Contact with Foods", which appears as an Annex and forms part of this Resolution.

Art. 2 - Repeal GMC Resolutions No. 19/94, 12/95, 35/97, 56/97, 52/99 and 20/00.

Art. 3 - The States Parties will indicate in the scope of the GTS N°3 the national organisms competent for the implementation of the present Resolution.

Article 4 - This Resolution shall apply in the territory of the States Parties, to trade among them and to imports outside the zone.

Art. 5 - This Resolution must be incorporated into the legal order of the States Parties before 31/III/2016.

XCIX GMC - Asuncion, 2/IX/15.

ANNEX

MERCOSUR TECHNICAL REGULATION ON CELLULOSIC **MATERIALS, PACKAGING AND EQUIPMENT INTENDED TO COME IN CONTACT WITH FOODS**

PART I

1. SCOPE

1.1. This Technical Regulation applies to materials, packaging and equipment whose face is intended to come in contact with the food or with food raw materials (hereinafter referred to as "food") is cellulosic or cellulosic coated or treated with waxes, paraffins, mineral oils and mineral pigments (coating) provided for in PART II of this Regulation. Hereinafter they will be referred to as cellulosic packaging and equipment.

1.2. It also applies to containers and equipment made up of layers of the same material or of different materials (multilayers), provided that those comply with the provisions of item 1.1.

1.3. It also applies to packaging and equipment containing cellulosic fibers from recycled material mentioned in item 1.2 of PART II of this Regulation - "Positive List of Components for Cellulosic Material, Packaging and Equipment in Contact with Foods".

1.4. This Technical Regulation does not apply to secondary packaging made from paper, paperboard or cardboard, provided it is ensured that they do not come into contact with food, do not interfere with the integrity of the food and do not transfer substances harmful to health.

1.5. This Regulation does not apply to cellulosic materials, packaging and equipment intended to come in contact with foods which must always be peeled for consumption, provided that it ensures that they do not modify the organoleptic characteristics of the food and do not transfer substances harmful to the Health.

1.6. This Technical Regulation does not apply to papers for filtration, infusion, baking and/or heating in microwave and/or conventional furnaces, which must meet the specific requirements described in the relevant MERCOSUR Technical Regulations.

1.7. Substances used for the manufacture of raw materials or for the formulation of active ingredients listed in PART II of this Regulation shall be used in accordance with the principles defined in item 2.2 of the General Provisions of this Regulation.

1.7.1 Only substances listed in item 4.5 of PART II of this Regulation may be used as antimicrobials.

2. GENERAL PROVISIONS

2.1. The cellulosic materials, packaging and equipment referred to in these Technical Regulations must be manufactured in accordance with Good Manufacturing Practices and be compatible with the use for direct contact with food.

2.2. Cellulosic materials, packaging and equipment, under the foreseeable conditions of use, should not transfer to food, substances which pose a risk to human health. In case of migration of substances, they should not cause an unacceptable modification of the composition or the sensory characteristics of the food.

2.3. For the manufacture of cellulosic materials, packaging and equipment intended to come into contact with food, only should be used those substances included in the "Positive List of Components for Cellulosic Material, Packaging and Equipment in Contact with Food" that is included in PART II of this Regulation. The manufactured materials must comply with the usage restrictions, migration limits and/or established composition limits.

2.4. Cellulosic materials, packaging and equipment coated or treated with waxes, paraffins, mineral oils and mineral pigments (*coating*) must comply with the restrictions set out in PART II of this Regulation.

2.5. Cellulosic packaging and equipment coated with compounds other than those provided for in item 2.4 must comply with the restrictions established in the Specific Technical Regulations relating to the coating material.

2.6. The use of food additives authorized by the MERCOSUR Technical Regulations, not mentioned in this list, is permitted provided they comply with the following:
a) The restrictions established for its use in food;
b) The quantity of the additive present in the food, added to which it may migrate from the package, does not exceed the limits established for each food.

2.7. In packaging and equipment made up of layers of the same material or of different materials (multilayers), those layers that do not come into direct contact with food must comply with the specific MERCOSUR Technical Regulations for each material or must ensure that there is no migration of substances in amounts which constitute a hazard to human health.

2.8. Composition and specific migration limits of the "Positive List of Components for Cellulosic Material, Packaging and Equipment in Contact with Food" refer to the papers, cardstock, paperboards, corrugated papers and molded pulps, among others, used in the manufacture of the packaging, hereinafter referred to as the finished product.

2.8.1. If not otherwise specified, the limits expressed as a percentage (%) refer to the mass/mass ratio (m/m) in the dry finished product.

2.8.2. In the case where the indicated values refer to the finished product, it is considered as dry finished product.

2.8.3. When the restriction refers to the extract of the finished product, the extract prepared according to the procedures mentioned in items 2.19.1 and 2.19.2 must be considered, depending on the intended condition(s) of use of the finished product. In case both conditions of use are foreseen, only the procedure of item 2.19.2 may be used.

2.9. Migration and composition limits of processing aids that could be used with more than one function are not cumulative. When the processing aid is used with more than one function, the maximum tolerable value must be the greater of the established limits.

2.10. The total migration limit for cellulosic packaging and equipment in direct contact with food is 8 mg/dm^2. The analytical tolerance of the method is 10%.

2.11. The total migration test must be performed in accordance with the procedure described in PART III.

2.12. In order to ensure the adhesion of the seals of the packaging, only adhesives whose components are included in the MERCOSUR Technical Regulation corresponding to the adhesives used in the manufacture of packaging and equipment in contact with foods are allowed.

2.13. For cellulosic packaging with two or more layers that use adhesives between them, the components of the adhesive(s) used must be included in the MERCOSUR Technical Regulation corresponding to adhesives used in the manufacture of packaging and equipment in contact with foods.

2.14. The same classifications of food and food simulants described in the MERCOSUR Technical Regulation for "Migration in materials, pacakging and plastic equipment intended to come into contact with food" are adopted for cellulosic packaging and equipment.

2.14.1. For fatty foods, n-heptane must be used as simulant and the reduction factors established for simulant D in the MERCOSUR Technical Regulation for "Migration in materials, packaging and plastic equipment intended to come in contact with food" should not be applied. In this case, the reduction factor defined in PART III of this Regulation should be used.

2.14.2. If waxes, paraffins and/or mineral oils form part of the composition of the sample, the correction must be made in accordance with the methodology described

in the Food and Drug Administration - FDA (Title 21 of the Code of Federal Regulations - CFR 176.170).

2.15. Cellulosic material, packaging and equipment intended to come into contact with food may use pigments and colorants complying with item 5.3 - "Pigments, colorants and fluorescent whitening agents" of the "Positive List of Components for Cellulosic Materials, Packaging and Equipment in Contact With Food" of PART II of this Regulation.

2.15.1 Pigments and colorants must not migrate according to the procedure described in *BS EN 646 - Paper and board intended to come into contact with foodstuffs - Determination of color fastness of paper and board.*

2.16. Cellulosic packaging and equipment intended to be come contact with foodstuffs may use fluorescent whiteners in their mass provided they comply with the limits established in the Positive List of this Regulation. Method of determination: Standard *EN 648 - Paper and board intended to come into contact with foodstuffs - Determination of the fastness of fluorescent whitened paper and board.*

2.17. Polychlorinated biphenyls at a total level of 5 mg/kg or more should not be detected in cellulosic packaging and equipment intended to come into contact with food. Method of determination: *BS EN ISO 15318 - Pulp, paper and board - Determination of 7 specified polychlorinated biphenyls.*

2.18 Levels equal to or greater than 0.15 mg/kg of pentachlorophenol in finished product should not be detected in cellulosic packaging and equipment intended to come into contact with food. Method of determination: *EN ISO 15320 - Pulp, paper and board - Determination of Pentachlorophenol in an aqueous extract.*

2.19. Cellulosic Packaging and equipment intended to come into contact with foodstuffs must comply with the following maximum limits for cadmium (Cd), Lead (Pb) and Mercury (Hg) in the cold or hot aqueous extract according to the proposed conditions of use:
a) Cadmium (Cd) = 0.5 µg/g of finished product;
b) Lead (Pb) = 3 µg/g of finished product;
c) Mercury (Hg) = 0.3µg/g of the finished product.

2.19.1. The extract used for the determination of metals must be obtained according to the procedure described in *BS EN 645: Paper and board intended to come into contact with foodstuffs - Preparation of cold water extract.*

2.19.2. The extract used for the determination of metals when the temperature of the different types of food in contact with the Cellulosic packaging or equipment is greater than 40ºC must be obtained according to the procedure described in *BS EN*

647: Paper and board intended to eat Into contact with foodstuffs - Preparation of hot water extract.

2.20. For the determination of the metals Cadmium (Cd), Lead (Pb) and Mercury (Hg), the respective procedures that are in the following norms must be observed:
BS EN 12498 - Paper and board intended to come into contact with foodstuffs - Determination of cadmium and lead in an aqueous extract.
BS EN 12497 - Paper and board intended to come into contact with foodstuffs - Determination of mercury in an aqueous extract.

2.21. The specific migration for arsenic (As) and chromium (Cr) must be determined in cellulosic materials, packaging and equipment intended to come into contact with food.

2.21.1 When cellulosic materials are intended to come into contact with foods with established contaminant limits, the levels of contaminants in packaged foods should not exceed the values established for that particular food.

2.21.2. In order to define the specific migration limit (LME) of arsenic (As), the value defined in the "MERCOSUR Technical Regulation on Maximum Limits of Inorganic Contaminants in Foods" should be used and if there is no such limit, the defined value in the national legislation, in accordance with the conversion defined in item 5 of PART III of these Technical Regulation. In the event that there is no limit for arsenic (As) in the MERCOSUR Technical Regulation, nor in national legislation, the specific migration limit 0.01 mg/kg should be taken.

2.21.3. In order to define the specific chromium (Cr) migration limit, the value defined in the "MERCOSUR Technical Regulation on Inorganic Contaminants in Foods Maximum Limits" should be used, if there is no such limit, use the value defined in the legislation According to the conversion defined in item 5 of PART III of these Technical Regulations. In case there is no limit for chromium (Cr) in the MERCOSUR Technical Regulation, nor in national legislation, the specific migration limit 0.05 mg/kg should be taken.

2.22. Specific migration may be determined for the items listed below, when present in the cellulosic material:
a) Antimony (Sb), LME 0.04 mg/kg
b) Boron (B), LME 0.5 mg/kg
c) Barium (Ba), LME 1 mg/kg
d) Copper (Cu), LME 5 mg/kg
e) Tin (Sn), LME 1.2 mg/kg
f) Fluorine (F), LME 0.5 mg/kg
g) Silver (Ag), LME 0.05 mg/kg
h) Zinc (Zn), LME 25 mg/kg

2.23. The specific migration testing for the elements mentioned in items 2.19, 2.21 and 2.22 must be performed with the simulant corresponding to the type of food with which the cellulosic material will be in contact.

2.23.1. If the type of food is not known, then simulant B will be used.

2.23.2. The use of simulant B excludes the need to carry out the test of specific migration of the elements mentioned in item 2.19, 2.21 and 2.22 with the simulants A, C and D because it is considered a more drastic extraction condition than the others.

2.23.3. The conditions of time and temperature are defined in TABLE 1 that is included in PART III of this Technical Regulation.

2.24. The determinations of the elements in the specific migration extracts should be performed using validated techniques of adequate sensitivity (such as absorption or atomic emission spectrometry).

2.25. The requirements established in items 2.19, 2.21 and 2.22 do not apply to cellulosic materials in contact with dry non-fatty foods.

2.26. Cellulosic packaging and equipment intended to come into contact with food must meet the limits established for organic compounds contemplated in the Positive List of this Regulation. For the determination of these compounds, specific recognized and validated methodologies must be used to allow the identification and adequate quantification of the compound.

2.27. Cellulosic packaging and equipment must not transfer antimicrobial agents used in the papermaking process to food. Method of determination: *BS EN 1104: Paper and board intended to come into contact with foodstuffs - Determination of transfer of antimicrobial constituents.*

2.28. Cellulosic packaging and equipment must have microbiological standards compatible with the food they contain or are intended to come into contact with.

2.29. The "Positive List of Components for Cellulosic Materials, Packaging and Equipment in Contact with Food" may be modified in the scope of MERCOSUR both for inclusion/exclusion of substances and for modification of its limits and other restrictions. For this purpose, the following references are considered: United States Food and Drug Administration (FDA), recommendations of the Bundesinstitut fur Risikobewertung (BfR) and Council of Europe, European Union legislation and Codex Alimentarius.

PART II

POSITIVE LIST OF COMPONENTS FOR CELLULOSIC MATERIALS, PACKAGING AND EQUIPMENT IN CONTACT WITH FOODS

1. FIBROUS RAW MATERIALS

1.1. Primary (first-use) cellulosic fibers of chemical, mechanical, semi-chemical, chemithermechanical, thermomechanical and chemimechanical pulp, bleached, semi-bleached or non-bleached pulp.

1.2. Secondary cellulosic fibers (already passed at least once by a paper machine), also called recycled fibers, which meet the following requirements:

a) Packaging made from recycled fibers and which come into contact with food must comply with the specifications of this Regulation.

b) In the formulation of packaging and equipment made with recycled cellulosic fibers, only the additives provided for in this "Positive List of Components for Cellulosic Material, Packaging and Equipment in Contact with Foods" may be incorporated, in compliance with the restrictions established therein.

c) The process discarding that returns to the same manufacturing circuit is considered reprocessing, and, for the purposes of this Regulation, it is not considered as recycled material.

d) In the manufacture of cellulosic packaging in contact with food, recycled fibers from the indiscriminate collection of residues, which may compromise safety or affect the organoleptic characteristics of food shall not be used.

e) Cellulosic material in contact with food using recycled fibers in its production must comply with the following maximum limits for specific migration:

Benzophenone: 0.6 mg/kg;

Bisphenol A: 0.6 mg/kg. Verification of the specific migration of this compound is necessary only for cellulosic materials in contact with aqueous or fatty foods;

- Phthalates:
Di-ethylhexyl phthalate: 1.5 mg/kg;
Di-n-butyl phthalate: 0.3 mg/kg;
Diisobutyl phthalate: 0.3 mg/kg;
The sum of di-n-butyl phthalate and diisobutyl phthalate should not exceed 0.3 mg/kg;

- 4,4 'bis (dimethylamino) benzophenone: <0.01 mg/kg. Verification of the specific migration of this compound is necessary only for cellulosic materials in contact with aqueous or fatty foods;

- Primary aromatic amines: they should not be detected. Verification of the specific migration of this compound is necessary only for cellulosic materials in contact with aqueous or fatty foods.

f) Cellulosic food contact material using recycled fiber in its production shall meet the following maximum limit for the contaminant: diisopropylnaphthalene: undetectable, where the available lowest detection limit method is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity must be established.

g) Particularly for dry and non-fatty food with a large surface area (e.g. flour, salt, rice, etc.), the migration of volatile and hydrophobic substances by air should be particularly considered.

1.3. Synthetic fibers of first use, provided they comply with the MERCOSUR Technical Regulations corresponding to the positive lists of additives, polymers, monomers and other starting substances for packaging and plastic equipment in contact with food.

1.4. Bleached vegetable fibers treated with sulfuric acid (parchment type or vegetal paper) must fulfill, in addition to the requirements established for all cellulosic materials, the following items:

a) Acidity expressed as sulfuric acid: maximum 0.02% (m/m);
b) Humidity: maximum 10.0% (m/m);
c) Ash: maximum 0,60% (m/m);
d) Dry residue of the aqueous extract obtained in hot: maximum 1.50% (m/m);
e) Reducing substances (expressed as glucose): maximum 0.20% (m/m);
f) Arsenic as As, composition limit: maximum 2 mg/kg;
g) Total copper as Cu, composition limit: maximum 30 mg/kg;
h) Water-soluble copper as Cu, specific migration limit: maximum 10 mg/kg;
i) Total iron as Fe, composition limit: maximum 70 mg/kg;
j) Water-soluble iron as Fe, specific migration limit: maximum 15 mg/kg;
k) Lead as Pb, composition limit: maximum 20 mg/kg;
l) Formaldehyde: maximum 1,0 mg of formaldehyde/dm^2 in the finished product;
m) Boric acid and other antiseptics: they should not be detected.

In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity must be established.

2. RAW MATERIAL ADDITIVES

2.1. Anthraquinone [CAS 84-65-1] (minimum purity 98%) as lignin and cellulose separation accelerator, max. 0.10% by weight of the lignocellulosic material.

2.1.1. In cellulosic materials, packaging and equipment intended to be come contact with food, the LME of 0.01 mg/kg of food must not be exceeded.

2.2. Xylanase. No residual enzymatic activity should be detected in the finished product.

2.3. Diethylene triamine pentamethylene phosphonic acid [CAS 15827-60-8], max. 0.22% on dry fiber basis.

2.4. Potassium sulphite, max. 0.01%

2.5. Tetrasodium iminodisuccinate, max. 0.17% on dry fiber basis.

2.6. Activated carbon [CAS 7440-44-0]. Must comply with specifications for its use in food processing.

3. LOADING MATERIALS
Natural and synthetic water-insoluble substances:

3.1. Calcium carbonate [CAS 471-34-1] or magnesium carbonate [CAS 546-93-0].

3.2. Silicon dioxide [CAS 7631-86-9].

3.3. Silicates of: sodium [CAS 1344-09-8], potassium [CAS 1312-76-1], magnesium [CAS 1343-88-0], calcium [CAS 1344-95-2], aluminum [CAS 1327-36- 2] and iron [CAS 10179-73-4] and/or [CAS 12673-39-1] and their mixed compounds (including natural minerals such as talc and kaolin).

3.4. Calcium sulphate [CAS 7778-18-9].

3.5. Calcium Sulfoaluminate (Satin White).

3.6. Barium sulphate [CAS 7727-43-7]. Maximum 0.01% barium soluble in 0.1M hydrochloric acid solution.

3.7. Titanium dioxide [CAS 13463-67-7].

3.8. Ferric Oxide.

3.9. Polyvinylidene chloride copolymer microspheres, methyl methacrylate and acrylonitrile, filled with isobutane, max. 1.5% dry fiber basis. The bis-(4-tert-

butylcyclohexyl)-peroxydicarbonate initiator can be used, max. 0.45% relative to the microspheres.

4. AUXILIARY SUBSTANCES

4.1. Surface and internal gluing agents

4.1.1. Refined rosin and tall oil, its products of addition of maleic acid [CAS 110-16-7] and/or fumaric acid [CAS 110-17-8] and/or formaldehyde [CAS 50-00-0] with rosin. The aqueous extract should not contain more than 1.0 mg/dm^2 of formaldehyde on the finished product basis.

4.1.2. Casein and animal glue, soy or protein corn.

4.1.3. Starch and starches.

4.1.3.1. Maximum limit of contaminants: Arsenic: 3 mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and Copper combined: 50 mg/kg.

4.1.3.2. The sum of the impurities mentioned in subitem 4.1.3.1 must be less than 50 mg/kg of starch.

4.1.3.3. Modified food starches and starches: degraded, etherified and esterified starches (including phosphates) and other starches, excluding starches and starches modified with boric acid and its compounds.

4.1.3.4. Starches and modified alimentary starches (e.g. cationic, amphoteric), treated with the reagents specified below, but complying with established starch composition determinations:

a) ammonium persulfate [CAS 7727-54-0]: shall not exceed 0.3% (m/m). In alkaline starches they should not exceed 0.6% (m/m).
b) (4-chlorobuten-2) trimethylammonium chloride: it should not exceed 5% (m/m). The starch mentioned herein should only be used in emulsion with the internal sizing agent.
c) 2-chloro-N, N-diethylethanamine hydrochloride [CAS 869-24-9]: should not exceed 4% (m/m).
d) dimethylaminoethyl methacrylate [CAS 2867-47-2]: must not exceed 3% (m/m).
e) 1,3-bis (hydroxymethyl)-2-imidazolidone [CAS 136-84-5]: must not exceed 0.375% (m/m). The starch mentioned herein should only be used in emulsion with the internal sizing agent.
f) 2,3-epoxypropyltrimethylammonium chloride [CAS 3033-77-0]: must not exceed 5% (m/m).
g) ethylene oxide [CAS 75-21-8]: in the modified starch, it must not exceed 3% (m/m) of the units derived from ethylene oxide.

h) phosphoric acid [CAS 7664-38-2] (not to exceed 6% (m/m)) and urea [CAS 57-13-6] (not to exceed 20% (m/m)). The starch mentioned herein should only be used in emulsion with the internal sizing agent and in the manufacture of packaging intended to come into contact with the following foods: dairy products and products thereof, water-in-oil emulsions with low or high fat content, low-moisture oils and fats, bakery products and dry solids with surfaces containing fatty substances or not.
i) vinyl acetate [CAS 108-05-4]: starch acetate, treated with this reagent. The starch should not contain more than 2.5% acetyl groups.
j) 3-chloro-2-hydroxypropyltrimethylammonium chloride [CAS 3327-22-8] or 2,3-epoxypropyltrimethylammonium chloride [CAS 3033-77-0]. The starch should not contain more than 4.0% (m/m) nitrogen and not more than 1 mg/kg epichlorohydrin [CAS 106-89-8].
k) propylene oxide [CAS 75-56-9]: for the preparation of neutral starch ethers. The starch should not contain more than 1 mg/kg of propylenchlorohydrin, with a maximum degree of substitution of 0.2%.
l) monochlorinated acetate (anionic ethers of starch). The starch must not contain more than 0.4% sodium glycollate with a maximum degree of substitution of 0.08%.
m) 3-chloro-2-hydroxypropyl trimethyl ammonium chloride and succinic anhydride [CAS 108-30-5]. The starch obtained may not contain more than 1 mg/kg of epichlorohydrin and 1.6% of nitrogen.
n) epichlorohydrin and 3-chloro-2-hydroxypropyl trimethyl ammonium chloride. The starch obtained should not contain more than 1 mg/kg epichlorohydrin and 0.5% nitrogen.
o) monoamide phosphate treated with 3-chloro-2-hydroxypropyl trimethyl ammonium chloride. The starch obtained should not contain more than 1 mg/kg epichlorohydrin and 0.5% nitrogen.
p) chlorine, such as sodium hypochlorite. The starch obtained should not contain more than 8.2 grams of chlorine per kilogram of dry starch.
q) sodium, potassium or ammonium peroxydisulfate, and/or peracetic acid and/or hydrogen peroxide.
r) ammonium phosphate or orthophosphoric acid in the presence of urea.

4.1.4. Cellulose ethers

4.1.5. Technically pure sodium carboxymethylcellulose salt. The sodium glycollate [CAS 2836-32-0] present in the carboxymethylcellulose should not exceed 12%.

4.1.6. Sodium alginates [CAS 9005-38-3], potassium [CAS 9005-36-1], ammonium [CAS 9005-34-9], calcium [CAS 9005-35-0] and 1,2-propanediol [CAS 9005-37-2] complying with the following maximum contaminant limits: arsenic: 3 mg/kg; Lead: 5 mg/kg; Mercury: 1 mg/kg; Cadmium: 1 mg/kg; Heavy metals (expressed as lead): 20 mg/kg.

4.1.7. Xanthan gum [CAS 11138-66-2]. Minimum content of pyruvic acid: 1.5%. Nitrogen content: must be less than 1.5%. Maximum residue of ethanol and isopropanol, alone or in combination: 500 mg/kg. Lead: maximum 2 mg/kg.

4.1.8. Galactomannans listed below, complying with the protein content specified for each type and with the following maximum contaminant limits: ethanol and isopropanol, alone or combined: 1%; Arsenic: 3 mg/kg; Lead: 5 mg/kg; Mercury: 1 mg/kg; Cadmium: 1 mg/kg; Heavy metals (expressed as lead): 20 mg/kg.

4.1.8.1. Tara gum. Maximum protein content: 3.5% (factor N × 5.7).

4.1.8.2. Carob gum [CAS 9000-40-2)]. Maximum protein content: 7% (N × 6.25 factor).

4.1.8.3. Guar gum [CAS 9000-30-0]]. Maximum protein content: 10% (N × 6.25 factor).

4.1.9. Galactomannan ethers:

4.1.9.1. Carboxymethylgalactomannan: residual sodium glycollate maximum content 0.5%.

4.1.9.2. Galactomannan treated with 3-chloro-2-hydroxypropyl-trimethylammonium chloride or glycidyl-trimethyl ammonium chloride. Epichlorohydrin content: maximum 1 mg/kg; Nitrogen content: maximum 4.0%.

4.1.9.3. Phosphoric acid ester and galactomannan. Maximum limit 0.25% on dry fiber basis.

4.1.10. Sodium silicate and alumina gel.

4.1.11. Dispersions of microcrystalline waxes and paraffins: maximum 2% in the paper mass or at the surface. Must comply with the MERCOSUR Technical Regulation referred to Waxes and Paraffins in contact with food.

4.1.12. Dispersions of plastic materials: must comply with the MERCOSUR Technical Regulation on Positive list of monomers, other starting substances and polymers authorized for the production of packaging and plastic equipment in contact with food and the MERCOSUR Technical Regulation on Positive List of Additives for Plastic Materials destined to the elaboration of packaging and equipment in contact with food. Additionally, the following may also be used as monomers:
a) 2-(Dimethylamino) ethyl acrylate, max. 0.01 mg/dm^2;
b) N-[3-(dimethylamino) propyl] methacrylamide;
c) 2-(N, N, N-trimethylammonium) ethylmethacrylate hydrochloride.

4.1.13. Alkylketene dimers with chain length of C10 to C22 alkyl radicals which may contain up to 65% isoalkyl groups. Maximum in mass: 1% on dry fiber basis.

4.1.14. Sodium and ammonium salts of mixed polymers of maleic acid monoisopropyl ester [CAS 924-83-4] (about 25%), acrylic acid [CAS 79-10-7] (approx. 16%) and styrene [CAS 100- 42-5] (approx. 59%). Maximum 0,5% in relation to the finished product.

5.1.15. Ammonium salt of a copolymer of maleic anhydride, monoisopropyl ester of maleic acid and diisobutylene. Maximum 0,5% in relation to the finished product.

4.1.16. Ammonium salt of a copolymer of styrene (approx. 60%), acrylic acid (about 23%) and maleic acid (approx. 17%). Maximum 0,5% in relation to the finished product.

4.1.17. Disodium salt of a mixed polymer of styrene (50%) and maleic acid (50%). Maximum 0.7% in relation to the finished product.

4.1.18. Cationic water-soluble polyurethanes obtained from glyceryl monostearate [CAS 123-94-4], toluene diisocyanate [CAS 584-84-9] and N-methyldiethanolamine [CAS 105-59-9] or anionic polyurethanes, soluble in water, obtained from glyceryl monostearate, toluene diisocyanate, dimethylpropionic acid [CAS 75-98-9] and N-methyldiethanolamine with an average molecular weight of 10,000 Daltons. Maximum 0.15% on dry fiber basis. In the manufacture of polyurethanes, the use of a maximum of 0.03% (m/m) of butyl tin diacetate [CAS 1067-33-0] as sizing agent is permitted. The finished product must not contain more than 0.3 µg/dm^2 of this substance. Primary aromatic amines (detection limit ≤ 0.1 mg/kg) should not be detected in the extract of the finished product.

4.1.19. Cationic polyurethanes, water soluble, obtained from glyceryl monostearate, toluene diisocyanate and N-methyl diethanolamine and cross-linked with epichlorohydrin. Average molecular weight 100,000 Dalton. Maximum 0.6% on dry fiber basis. Epichlorohydrin (detection limit: 1 mg/kg) should not be detected. In the manufacture of polyurethanes, the use of a maximum of 0.03% (m/m) of butyltin diacetate as the sizing agent is allowed. The paper should not contain more than 0.3 µg/dm^2 of this substance. Primary aromatic amines should not be detected in the extract of the finished product. No ethylenimine should be detected in the resin (limit of detection 0.1 mg/kg). 1,3-Dichloro-2-propanol should not be detected in the extract of the finished product (limit of detection 2 µg/l). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

4.1.20. Copolymer of maleic acid and dicyclopentadiene (ammonium salt), max. 2.0 mg/dm^2 in the finished product.

4.1.21. 3-alkenyl (C 15 -C 21) -dihydrofuran-2,5-dione, max. 1.0% on dry fiber basis.

4.1.22. Acrylamide copolymer [CAS 79-06-1] and acrylic acid [CAS 79-10-7], crosslinked with N-methylene-bis (acrylamide) [CAS 110-26-9], max. 1.0% on dry fiber basis.

4.1.23. Acrylamide copolymer, 2-[(methacryloyloxy) ethyl] trimethyl ammonium chloride, N,N'-methylene bis-acrylamide and itaconic acid [CAS 97-65-4], max. 1.0% on dry fiber basis.

4.1.24. Acrylamide copolymer, 2-[(methacryloyloxy) ethyl] trimethyl ammonium chloride, N,N'-methylene bis-acrylamide, itaconic acid and glyoxal [CAS 107-22-2], max. 1.0% on dry fiber basis.

4.1.25. Product of the addition of fumaric acid [CAS 110-17-8] with rosin, cross-linked with triethanolamine [CAS 102-71-6], max. 4.0% on dry fiber basis.

4.1.26. Natural fatty acid anhydrides, max. 0.2% on dry fiber basis.

4.1.27. 2-stearoyl lactylate, as an emulsifier for sizing agent, maximum 0.02% in the formulation.

4.1.28. Mixture of (2-Alkenyl) succinic anhydrides, in which the alkenyl groups are derived from olefins containing at least 95% C15-C21 groups. For use only as internal sizing agent. Maximum 1% in the finished product.

4.1.29. Condensation products of melamine, formaldehyde and omega-paraminocaproic acid, max. 1%. In the aqueous extract of the finished product no more than 1.0 mg formaldehyde/dm^2 should be detected.

4.1.30. Cereal flour:
a) treated with acids;
b) treated with monochloroacetic acid to produce anionic ethers of cereal flour (specification: sodium glycolate max 0.4%, degree of substitution max 0.08%);
c) treated with glycidyl trimethyl ammonium chloride (specification: epichlorohydrin, max 1 mg/kg).

4.1.31. Hydroxyethylamide.

4.1.32. Anhydrides (2 Alkenyl) succinic anhydrides in which the alkenyl groups are olefin derivatives containing at least 78% C30 or higher groups [CAS 70983-55-0]. Only for contact with dry foods.

4.1.33. 2-oxetanone, 3-(C6-16 and C16-alkyl unsaturated) 4-(C7-17 and C17 and unsaturated alkylidene) derivatives [CAS 863782-35-8]. Max. 0.4% (w/w) of the finished product.

4.1.34. 2,4,7,9-tetramethyl-5-decyne-4,7-diol [CAS 126-86-3].

4.1.35. Salts of fatty acids (C12 to C20) of ammonium, aluminum, calcium, potassium and sodium. For calcium stearate [CAS 1592-23-0], the use of n-decanol [CAS 112-30-1] as a stabilizing agent for the dispersion is permitted. The substances provided for in this item must comply with the purity requirements of food additives.

4.1.36. Anhydrides (2 Alkenyl) succinic anhydrides in which alkenyl groups are olefin derivatives containing at least 95% C15 to C21 groups. Maximum 1% (m/m) of finished product.

4.2. Retention and Drainage Agents

4.2.1. Homopolymers and copolymers of:
a) Acrylamide.
b) Acrylic acid.
c) 3- (N, N, N-trimethylammonium) propylacrylamide hydrochloride.
d) 2- (N, N, N-trimethyl ammonium) ethylacrylate chloride [CAS 44992-01-0].
e) 2- (N, N, N-trimethyl ammonium) ethyl methacrylate hydrochloride.
f) 2- (N, N-Dimethyl-N-benzylammonium) ethylacrylate chloride [CAS 46830-22-2].

Maximum 0.1% on dry fiber basis. The polymers shall not contain more than 0,1% of the acrylamide monomer and not more than 0.5% of the monomers listed under b) to f). The migration of paraffinic and naphthenic (C10 to C16) solvents used in the formulation of these retention and drainage agents should not exceed 12 mg/kg feed in the finished product. The migration of paraffinic and naphthenic (C16 to C20) solvents used in the formulation of these retention and drainage agents should not exceed 4 mg/kg of food in the finished product.

4.2.2. Polyethylenimine: maximum 0.5% on dry fiber basis. Ethyleneimine [CAS 151-56-4] should not be detected (limit of detection: 0.1 mg/kg).

4.2.3. Lignosulfonic acids, as well as their ammonium, calcium, magnesium and sodium salts, maximum 1% total on dry fiber basis.

4.2.4. Cross-linked cationic polyalkylamines and amides. Maximum limit: 4%, dry fiber basis, for all the additives formed by the items listed below:

a)Polyamine-epichlorohydrin resin synthesized from epichlorohydrin and diaminopropylmethylamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

b) Polyamide-epichlorohydrin resin synthesized from epichlorohydrin, adipic acid [CAS 124-04-9], caprolactam [CAS 105-60-2], diethylenetriamine [CAS 111-40-0] and/or ethylenediamine [CAS 107- 15-3]. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

c) Polyamide-epichlorohydrin resin synthesized from adipic acid, diethylenetriamine and epichlorohydrin or a mixture of epichlorohydrin and ammonia. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

d) Polyamide-polyamine-epichlorohydrin resin synthesized from epichlorohydrin, adipic acid dimethyl ester [CAS 627-93-0] and diethylenetriamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

e) Polyamide-polyamine-dichloroethane resin synthesized from dichloroethane and an adipic acid amide, caprolactam and diethylenetriamine.

f) Polyamide-epichlorohydrin resin synthesized from epichlorohydrin, diethylenetriamine, adipic acid and ethyleneimine, maximum 0.5% on dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

g) Polyamide-epichlorohydrin resin synthesized from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine [CAS 124-40-3]: maximum 0.2% on based fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-

chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

h) Polyamine-epichlorohydrin resin, synthesized from polyepichlorohydrin, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine: max. 0.2% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

i) Polyamide-epichlorohydrin resin synthesized from epichlorohydrin, diethylenetriamine, adipic acid, ethyleneimine and polyethylene glycol: maximum 0.2% on dry fiber basis. No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg / kg) and 1,3-dichloro-2-propanol (detection limit 2 µg/l). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

j) Polyamide-polyamine-epichlorohydrin resin synthesized from epichlorohydrin, adipic acid dimethyl ester, glutaric acid dimethyl ester and diethylenetriamine: maximum 2% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

k) Polyamide-polyamine-dichloroethane resin synthesized from adipic acid, diethylenetriamine and 1,2-dichloroethane: max. 0.2% on dry fiber basis.

l) Polyamide-polyamine-dichloroethane resin synthesized from adipic acid, diethylenetriamine and a mixture of ethylenediamine, diethylenetriamine, triethylenetetramine [CAS 112-24-3], tetraethylenepentamine [CAS 112-57-2], pentaethylenehexamine [CAS 4067-16 -7], aminomethylpiperazine [CAS 6928-85-4] and 1,2-dichloroethane [CAS 107-06-2]: maximum 0.2% on dry fiber basis.

m) Polyamine-dichloroethane resin, synthesized from bis (3-aminopropyl) methylamine [CAS 105-83-9] and 1,2-dichloroethane: max. 0.2% on dry fiber basis.

n) Amine-polyetheramine-epichlorohydrin polyamide resin synthesized from diethylenetriamine, caprolactam, adipic acid, polyethylene glycol and epichlorohydrin: maximum 0.2% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1

mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

o) Polyamide-amine-ethyleneimine resin, synthesized from adipic acid, ethylenediamine and N-(2-aminoethyl)-1,3-propylenediamine, N,N '-[bis- (3-aminopropyl)]-1,2-ethylenediamine, epichlorhydrin, ethyleneimine and polyethylene glycol: max. 0.2% on dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

4.2.5. High molecular weight cationic polyamidamine synthesized from triethylenetetramine and adipic acid with 15% diethyleneglycol monomethyl ether as diluent or a mixture of 70 parts of polyamide amine solution with 30 parts of sulphated cetacean oil: maximum 0.2% calculated as polyamidamine on dry fiber basis.

4.2.6. Mixtures of:

a) Polyamide-epichlorohydrin resin synthesized from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine (maximum 0.05% on dry paper basis), high molecular weight linear polyoxyethylene (maximum 0.015% on dry paper basis) and a condensation product of xylenesulfonic acid [CAS 25321-41-9] dihydroxydiphenylsulfone and formaldehyde (sodium and ammonium salts) (maximum 0,1% on dry paper basis). They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

b) Polyamide-epichlorohydrin resin, prepared from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine (maximum 0.05% based on dry paper), high molecular weight linear polyoxyethylene (maximum 0.015% on dry paper basis) and a condensation product of 2-naphthalenesulfonic acid [CAS 120-18-3], phenol [CAS 108-95-2] and formaldehyde, as sodium salt (maximum 0.06% on dry paper basis). They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the

aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

4.2.7. Polyacrylamide reaction product with formaldehyde and dimethylamine: maximum 0.06% referred to the finished product. The residual content of the acrylamide monomer should not exceed 0.1% referred to the product of the reaction of the polyacrylamide with formaldehyde and dimethylamine. In the aqueous extract of the finished product no dimethylamine (detection limit: 0.002 mg/dm^2) should be detected. In the extract of the finished product a maximum of 1.0 mg/dm^2 of formaldehyde can be detected.

4.2.8. Alkylarylsulfonates. Maximum limit 1.0% in the formulation on dry fiber basis and must be eliminated in the paper-making process.

4.2.9. Paraffinic silicone dispersions. Maximum limit 0.5% in the formulation referred to on dry fiber basis of the dispersion. The silicone must meet the requirements specified in item 4.4.1.

4.2.10. Poly (oxyethylendimethylimine) dichloride ethylene (dimethylimine) ethylene dichloride. Maximum limit 0.1% (m/m) in the finished product.

4.2.11. Polyamine-epichlorohydrin resin synthesized by the reaction of epichlorohydrin with N, N, N, N-tetramethylethylenediamine [CAS 110-18-9] and monomethylamine [CAS 74-89-5], with a nitrogen content between 11.6% and 14.8%, chlorine content between 20.8% and 26.4% and a minimum viscosity in aqueous solution of 25% (w/w) of 500 centipoise at 25°C, determined with a Brookfield LV series viscometer, using a Rod nº 2 and rotation of 12 rpm. Maximum limit: 0.12% on the finished product.

4.2.12. Guar gum modified by treatment with 2-chloro-N, N-diethylethanamine hydrochloride. Used only as a retention and drainage agent.

4.2.13. Guar gum modified by treatment with less than 25% (w/w) of 2,3-epoxypropyltrimethylammonium chloride: the finished product should not contain more than 4.5% chlorine and 3% nitrogen, minimum viscosity in aqueous solution At 1% (m/m) of 1000 mPa.s at 25°C, using a Brookfield viscometer, RV series, with a nº 4 stem and a rotation of 20 rpm. It should not exceed 0,15% of the formulation on the dry fiber basis. Up to 0.3% (m/m) may be used for paper, paperboard and paperboard intended to come into contact with non-alcoholic and non-fatty foods, including: acidic and non-acidic aqueous foods (may contain salt and sugar), including oil-in-water emulsions; wet bakery products which do not contain fats or oil on the surface and dry solid foods which do not contain fat or oil on the surface.

4.2.14. Copolymer of dimethylamine and epichlorohydrin: maximum 0.25% on dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol

(limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

4.2.15. Copolymer of dimethylamine, ethylenediamine and epichlorohydrin [CAS 42751-79-1]: maximum 3% on dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

4.2.16. Homopolymers and copolymers of vinylformamide [CAS 13162-05-5] and vinylamine, maximum limit 0.2% on dry fiber basis.

4.2.17. Copolymer of acrylamide [CAS 79-06-1] and diallyldimethylammonium chloride [CAS 7398-69-8]. Maximum limit 0.02% in the formulation on dry fiber basis.

4.2.18. Polydimethyldiallylammonium chloride. Maximum limit 0.15% on dry fiber basis.

4.2.19. Sodium silicate stabilized with 0.42% of sodium tetraborate.

4.2.20. Poly (N-vinylformamide), 20-100% hydrolyzed, chloride salts [CAS 183815-54-5] or sulfate [CAS 117985-59-8]. For use in levels not exceeding 1.5% of the weight in the finished product.

4.2.21. Polyamidoamine-ethyleneimine-epichlorohydrin resin prepared by the reaction of hexadioic acid, N-(2-aminoethyl)-1,2-ethanediamine, (chloromethyl) oxirane, ethyleneimine (azeridine) and polyethylene glycol partially neutralized with sulfuric acid [CAS 167678- 45-7]. Maximum 0.12% of resin in the finished product.

4.2.22. Diethanolamine [CAS 111-42-2]. Only for use as an adjuvant to *pitch* control.

4.2.23. Copolymer of vinylamine-diallyl dimethyl ammonium chloride, obtained by the Hofmann degradation reaction, two amide groups of a copolymer of acrylamide-diallyl dimethyl ammonium chloride. Maximum limit 0.5% dry fiber basis.

4.2.24. Copolymer of acrylamide and ethyl 2- (N, N, N-trimethyl ammonium) acrylate. Maximum limit 1%, provided that the polymers contain not more than 0.1% of acrylamide monomer and 0.05% of 2-(N,N,N-trimethyl ammonium) ethyl acrylate.

4.2.25. Cellulose. No residual enzymatic activity should be detected in the finished product.

4.2.26. Acrylamide copolymer [CAS 79-06-1] and diallylamine [CAS 124-02-7], sulphate salt, using ammonium persulfate [CAS copolymer CAS 1355214-14-0] as the initiator. Maximum limit of 0.02% in the formulation on dry fiber basis.

4.3. Dispersing and flotation agents

The auxiliary additives mentioned in items 4.3.1. to 4.3.9. can be used at no more than 1% of each and the total should not exceed 3%, dry fiber basis.

4.3.1. Polyvinylpyrrolidone. Minimum molecular weight of 11,000 Daltons.

4.3.2. Alkylsulfonates (C10 to C20).

4.3.3. Alkylarylsulfonates. Maximum limit 1.0% dry fiber basis. They must be removed in the papermaking process.

4.3.4. Alkaline salts of phosphoric acids predominantly of linear condensation (polyphosphates). The content of cyclic condensed phosphates (metaphosphates) should not exceed 8%.

4.3.5. Sulphonated castor oil and sulfated castor oil.

4.3.6. Condensation products of aromatic sulphonic acids with formaldehyde. In the extract of the finished product no more than 1.0 mg/dm^2 of formaldehyde can be detected.

4.3.7. Lignosulfonic acid and salts of calcium, magnesium, sodium and ammonium.

4.3.8. Sodium laurilsulfate [CAS 151-21-3].

4.3.9. Sodium polyacrylate. Maximum limit 0.5% dry fiber basis.

4.3.10. Sodium dioctylsulfosuccinate [CAS 577-11-7].

4.3.11. Polyethyleneimine. Maximum limit 0.5% dry fiber basis. No ethylenimine should be detected in the resin (limit of detection 0.1 mg/kg).

4.3.12. Ethers of alkyl polyglycols (C13) with 5-7 oxyethylenic groups and 1-2 terminal groups of oxypropylene. Maximum limit 0.014% on dry fiber basis.

4.3.13. Citric acid [CAS 77-92-9].

4.3.14. 1,2-dihydroxy-C12 -C14 -alkyloxyethylates. Maximum limit 1.0% on dry fiber basis.

4.3.15. 2-amino-2-methyl-1-propanol [CAS 124-68-5]. Maximum limit 0.25 mg/dm^2 in the extract of the finished product.

4.3.16. 2-Phosphonobutane-1,2,4-tricarboxylic acid [CAS 37971-36-1]. Maximum limit 0.01% in the formulation on dry fiber basis.

4.3.17. Polyaspartic acid. Maximum limit 0.5% on dry fiber basis.

4.3.18. Polyoxypropylene-polyoxyethylene block copolymer (min. Molecular weight 6,800 Dalton).

4.3.19. Reaction product of 2-ethylhexylglycidyl ether with polyethylene glycol, max. 0.71 mg/dm^2. The reaction product must meet the following specifications:
- Number average molecular weight (Mn) ≥ 9,000 Dalton +/- 1,500 Dalton;
- Average molecular weight (Mw) ≥ 10,000 Dalton +/- 1,500 Dalton;
- Polydispersity index (Mw/Mn) = 1.0-1.3;
- 2-Ethylhexylglycidyl ether should not be detectable in the finished product (limit of detection: <0.02 µg/dm^2 paper).

4.3.20. Esters of fatty acids with mono and polyhydric alcohols (C 1 -C 18) and esters of fatty acids with polyethylene glycol and polypropylene glycol. Maximum limit 0.01% on dry fiber basis.

4.3.21. Xylanase. No residual enzyme activity should be detected in the finished product.

4.3.22. Cellulase. No residual enzyme activity should be detected in the finished product.

4.3.23. (Levan)-polysaccharide hydrolase fructose, 12.5 mg dry substance per kg of paper. It should not contain more than 1 unit of levanase activity per gram of paper.

4.3.24. Glycerin [CAS 56-81-5].

4.3.25. Polyethylene glycol [CAS 25322-68-3].

4.3.26. Mono-, di- and tri-propylene glycol methyl ether, only for use in contact with dry solid foods. The amount of that substance during the manufacturing process must not exceed the amount needed to accomplish the desired technical effect.

4.3.27. Monoisopropanolamine [CAS 78-96-6], for use as a dispersant for titanium dioxide suspension, max. 0.68% by weight of titanium dioxide. Only for use in contact with food at room temperature or below.

4.3.28. Aliphatic polyoxyethylene ethers.

4.3.29. Alpha amylase [CAS 9000-90-2].

4.3.30. 9-Octadecenoic acid (Z) -, reaction product with diethylenetriamine, cyclized, di-ethyl sulfate-quaternized [CAS 68511-92-2] and amides, unsaturated C18 and C18, N-(2-(2-(C17 C 17 unsaturated alkyl)-4,5-dihydro-1H-imidazol-1-yl) ethyl) [CAS 71808-32-7]. For use as a debonding agent. Maximum limit 0.5% in the finished product.

4.3.31. Sodium or ammonium salts of maleic anhydride-diisobutylene copolymer [CAS 37199-81-8]. For use in contact with dry foods. The amount of that substance should not exceed the amount needed to accomplish the desired technical effect.

4.3.32. Polyoxyethylene [CAS 68441-17-8].

4.3.33. Alcohol sulfate sodium salt of polyoxyethylated rosin (40 moles). The amount of that substance in the finished product should not exceed 300 ppm.

4.3.34. Polyethylene glycol ester with castor oil. Maximum limit of 5 mg/dm^2 of finished product.

4.3.35. Polyethylene glycol ethers (EO = 1-20) of straight chain or primary branched alcohols (C8-C26), max. 0.3 mg/dm^2, and polyethylene glycol ethers (EO> 20) of Linear chain or with primary branches, max. 5 mg/dm^2.

4.3.36. 2-aminoethanol. Maximum limit 0,41 mg/dm^2 in the finished product.

4.4. Antifoams

4.4.1. Organopolysiloxanes with methyl, dimethyl and/or phenyl groups (silicone oils) with a viscosity of at least 100 mm^2-s^{-1} at 20^{o}C. Maximum limit 0.1% on dry fiber basis.

4.4.2. Tributylphosphate [CAS 126-76-8] and / or triisobutylphosphate [CAS 126-71-6]. Maximum limit 0.1% dry fiber basis.

4.4.3. Aliphatic alcohols (C8-C26) in the esterified form. Up to 2% of paraffin and 2% of alkylaryloxyethylates and their esters with sulfuric acid (as emulsifiers) may be added in 20-25% aqueous solution of the antifoaming agent. Liquid paraffin must comply with the requirements established in the MERCOSUR Technical Regulation on paraffins in contact with food. Maximum limit 0.1% dry fiber basis.

4.4.4. Esters of fatty acids with mono and polyhydric alcohols (C 1 -C 22) and esters of fatty acids with polyethylene glycol and polypropylene glycol. Maximum limit 0.1% dry fiber basis.

4.4.5. Alkylsulfonamides (C10 to C20). Maximum limit 0.1% dry fiber basis.

4.4.6. Liquid paraffins. Maximum limit 0.1% dry fiber basis. They must comply with the MERCOSUR Technical Regulation on paraffins in contact with food.

4.4.7. Jelly. Maximum limit 0.1% dry fiber basis.

4.4.8. Silica. The amount of this antifoam agent added during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.9. Mono-, di-, triglycerides and fatty acids, alcohols and dimers, derived from: bovine fat, pig fat, cottonseed, rice, coconut, maize, peanut, rapeseed, linseed, palm, ricin, soybean, mustard, fish, cetacean and tall oil. The amount of antifoaming agent added during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.10. Reaction products of dimethyl and methylhydrogen siloxanes and silicones with polyethylene glycol-polypropylene glycol monoalylethers. The amount of anti-foaming agent added during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.11. Oil waxes. They must comply with the specifications established in the MERCOSUR Technical Regulation on paraffins in contact with food and the amount added during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.12. Mineral oil: it should not exceed the amount needed to accomplish the desired technical effect.

4.4.13. Kerosene: should not exceed the amount needed to accomplish the desired technical effect.

4.4.14. Copolymers of glycerol with ethylene oxide and propylene oxide, esterified with coconut oil or oleic acid. Maximum limit for each 0.075% dry fiber basis.

4.4.15. N, N'-ethylene di-stearamide [CAS 110-30-5].

4.4.16. Sorbitan monostearate [CAS 1338-41-6], polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan monooleate. Maximum limit for each 10 mg/dm^2 dry fiber basis.

4.4.17. Sorbitan monooleate [CAS 1338-43-8]. Maximum limit 0.1% dry fiber basis.

4.4.18. Stearyl alcohol [CAS 112-92-5].

4.4.19. Butyl hydroxy toluene [CAS 128-37-0].

4.4.20. Ethanol [CAS 64-17-5], to be used only as antifoaming agent in paper coatings. The added amount of this defoaming agent during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.21. Mixture of alcohols and ketone alcohols (distillation residues of C12-C18 alcohols). The added amount of this defoaming agent during the manufacturing process should not exceed the amount needed to accomplish the desired technical effect.

4.4.22. Reaction products between the substances provided for in item 4.4.9 and one or more of the following substances, with or without dehydration, being able to form compounds of the categories indicated in parentheses:
a) Aluminum hydroxide (soaps);
b) Ammonium (amides);
c) Butanol (esters);
d) Butoxy-polyoxypropylene, molecular weight 1,000-2,500 (esters);
e) Butylene glycol (esters);
f) Calcium hydroxide (soaps);
g) Diethanolamine (amides);
h) Diethylene glycol (esters);
i) Ethylene glycol (esters);
j) Ethylene oxide (esters and ethers);
k) Glycerin (mono- and diglycerides);
l) Hydrogen (amines and hydrogenated compounds);
m) Isobutanol (esters);
n) Isopropanol (esters);
o) Magnesium hydroxide (soaps);
p) Methanol (esters);
q) Morpholine (soaps);
r) Oxygen (oxidized oils);
s Pentaerythritol (esters);
t) Polyoxyethylene, molecular weight 200, 300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters);
u) Polyoxypropylene, molecular weight 200-2,000 (esters);
v) Potassium hydroxide (soaps);

w) Propanol (esters);
x) Propylene glycol (esters);
y) Propylene oxide (esters);
z) Sodium hydroxide (soaps);
aa) Sorbitol (esters);
bb) Sulfuric acid (sulphonated and sulphonated compounds);
cc) Triethanolamine (amides and soaps);
dd) Triisopropanolamine (amides and soaps);
ee) Trimethyl ether
ff) Zinc hydroxide (soaps).

The amount of antifoam agent added during the manufacturing process must not exceed the amount needed to accomplish the desired technical effect.

4.4.23. Caprylic alcohol [CAS 111-87-5].

4.4.24. Tridecyl alcohol [CAS 26248-42-0] and ethoxylated tridecyl alcohol (3-15 moles) [CAS 24938-91-8].

4.4.25. Polyoxypropylene-polyoxyethylene polymer (minimum molecular weight 950) [CAS 9003-11-6].

4.4.26. Polyoxyethylene monoleate (min. 8 moles).

4.4.27. Mono-, di- and tri-isopropanolamine.

4.4.28. Propylene glycol. Maximum limit 1 mg/dm^2 of finished product.

4.4.29. Polyethylenepropylene glycol. Maximum limit 1 mg/dm^2 of finished product.

4.4.30. a) 2,4,7,9-tetramethyl-5-decyne-4,7-diol;
b) 3,6-dimethyl-4-octyne-3,6-diol;
c) 2,5,8,11-tetramethyl-6-dodecyne-5,8-diol.

The specific migration limit of the summation of the three substances is 0.05 mg/kg of food.

4.5. Antimicrobial Agents

4.5.1. Enzymatic agents: fructose polysaccharide (levan)-hydrolase, max. 12.5 mg of dry substance per kg of paper. It should not contain more than 1 unit of levanase activity per gram of paper.

4.5.2. Active antimicrobial agents:

4.5.2.1 Sodium Chlorite [CAS 7758-19-2], Sodium Peroxide [CAS 1313-60-6] and Hydrogen [CAS 7722-84-1], Sodium Acid Sulphite [CAS 7631-90-5] , Acetic acid [64-19-7] and peracetic acid [CAS 79-21-0]. Maximum limit 0.1% in the formulation on dry fiber basis.

4.5.2.2. Aqueous solution of 0.15% p-hydroxybenzoic acid esters (methyl esters [CAS 99-76-3], ethyl esters [CAS 120-47-8] and n-propyl esters [CAS 94-13-3] as well as their sodium salts) in hydrogen peroxide (35% (m/m)). Maximum limit 15 mg of ester per kilogram of finished product and should not exert a preservative effect on the food. No peroxides should be detected in the extract of the finished product.

4.5.2.3. 1,4-Bis- (bromoacetoxy) butene: no more than 0.01 mg of bromine per dm^2 must be detected in the extract of the finished product.

4.5.2.4. Tetramethylthiourea disulfide [CAS 137-26-8]. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.5. 3,5-dimethyl-tetrahydro-1,3,5-thiadiazin-2-thione [CAS 533-74-4]. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.6. 2-bromo-4-hydroxyacetophenone [CAS 2491-38-5]. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.7. Disodium cyanodithioimidocarbonate [CAS 138-93-2] and/or potassium N-methyl dithiocarbamate [CAS 137-41-7]. These auxiliary substances should not be detected in the extract of the finished product when using the method with lowest limit of detection. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.8. Methylen-bis-thiocyanate [CAS 6317-18-6]. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.9. Potassium N-hydroxymethyl-N'-methyl dithiocarbamate [CAS 51026-28-9] and sodium 2-mercaptobenzothiazole [CAS 2492-26-4]. None of the two substances and their transformation products (in particular methylthiourea [CAS 598-52-7], N, N'-dimethylthiourea [CAS 534-13-4] and dithiocarbamate) should be detected in the extract of the finished product when the method with lowest limit of detection is used. In the validation of the method (s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.10. 2-Oxo-2- (4-hydroxy-phenyl)-acetylhydroxamic acid chloride. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.11. 2-Bromo-2-nitro-1,3-propanediol [CAS 52-51-7]. Maximum limit 0.003% in the formulation on a dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.12. Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [CAS 26172-55-4] (about 3 parts) and 2-methyl-4-isothiazolin-3-one [CAS 2682-20-4] (About 1 part). No more than 0.5 μg/dm^2 of isothiazolinones should be detected in the extract of the finished product.

4.5.2.13. 2,2-Dibromo-3-nitrile-propionamide [CAS 10222-01-2]. Maximum limit 0.0045% in the formulation on dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.14. Mixture of phenyl-(2-chloro-2-cyano vinyl) sulfone (about 80%), phenyl-(1,2-dichloro-2-cyano vinyl) sulfone (about 10%) and 2-phenylsulfonylpropionitrile [CAS 24224-99-5] (about 10%). Maximum total limit 0.001% in the formulation on dry fiber basis. These substances and the phenyl sulfonylacetonitrile decomposition product [CAS 7605-28-9] should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.15. 1,2-benzoisothiazolin-3-one [CAS 2634-33-5]. This auxiliary substance should not be detected in the extract of the finished product in an amount greater than 10 μg/dm^2.

4.5.2.16. 1,2-dibromo-2,4-dicyanobutane [CAS 35691-65-7]. Maximum limit 0.005% in the formulation on dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product in an amount greater than 0,6 $\mu g/dm^2$.

4.5.2.17. 4,5-dichloro- (3H) -1,2-dithiol-3-one [CAS 1192-52-5]. Maximum limit 0.004% in the formulation on dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product in an amount greater than 2.0 mg/kg dry fiber.

4.5.2.18. B-bromo-β-nitrostyrene [CAS 7166-19-0]. Maximum limit 0.045% in the formulation on dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product in an amount greater than 0.06 mg/kg of paper.

4.5.2.19. Glutaraldehyde [CAS 111-30-8]. Maximum limit 2.5% in the formulation on dry fiber basis. This auxiliary substance should not be detected in the extract of the finished product in an amount greater than 2 mg/kg.

4.5.2.20. Didecyldimethyl ammonium chloride [CAS 7173-51-5]. Maximum limit 0.05% in the formulation on dry fiber basis.

4.5.2.21. Potassium N-hydroxymethyl-N'-methyl dithiocarbamate [CAS 51026-28-9]. This agent must be added to the water used in the paper, paperboard and cardboard manufacturing process and the amount used should not exceed what is nedeed to accomplish the desired technical effect.

4.5.2.22. N-C12-C18 alkyl dimethylbenzyl ammonium chloride. This agent must be added to the water used in the paper, paperboard and cardboard manufacturing process and the amount used should not exceed the amount needed to accomplish the desired technical effect.

4.5.2.23. Sodium and potassium dimethyldithiocarbamate [CAS 128-03-0]. This agent must be added to the water used in the paper, paperboard and cardboard manufacturing process and the amount used should not the amount needed to accomplish the desired technical effect.

4.5.2.24. N- (2-p-Chlorobenzylethyl) -hexamino chloride. The product of the fragmentation, 2-(p-chlorobenzoyl)-ethylamine, should not be detectable in the methanol extract. In addition, the extract of the finished product should not contain more than 1.0 mg/dm^2 of formaldehyde.

4.5.2.25. 1-bromo-3-chloro-5,5-dimethylhydantoin [CAS 16079-88-2]. Maximum limit 0.04% in the formulation on dry fiber basis. Hypochlorite and hypobromite should not be detected in the extract of the finished product.

4.5.2.26. 2- (thiocyanomethylthio) benzothiazole [CAS 21564-17-0]. Maximum limit 0.00045% in the formulation on dry fiber basis.

4.5.2.27. Tetrakis (hydroxymethyl) phosphonium sulfate [CAS 55566-30-8]. Maximum limit 0.15 ppm in the extract of the finished product.

4.5.2.28. Mixture of 1,3-dichloro-5-ethyl-5-methylhydantoin [CAS 89415-87-2], 1,3-dichloro-5,5-dimethylhydantoin [CAS 118-52-5] and 1-bromo-3- Chloro-5,5-dimethylhydantoin [CAS 16079-88-2] in ratio 1:3:6. Maximum limit 0.04% in the formulation on dry fiber basis. Hypochlorite or hypobromite should not be detected in the extract of the finished product when the method with lowest limit of detection available is used. In the validation of the method(s) used, the limit of detection of the substance must be determined and the parameters of confirmation of its identity should be established.

4.5.2.29. Mixture of 1,3-dichloro-5-ethyl-5-methylhydantoin and 1,3-dichloro-5,5-dimethylhydantoin in a ratio of 1: 5. Maximum limit 0.04% in the formulation on dry fiber basis.

4.5.2.30 Compound of ammonium bromide/sodium hypochlorite [CAS 12124-97-9], maximum 0.02% in the formulation on dry fiber basis (active substance expressed as chlorine).

4.5.2.31. 4,5-dichloro-2-n-octyl-2H-isothiazol-3-one [CAS 64359-81-5], the amount in the extract of the finished product should not exceed 5 μg/dm^2.

4.5.2.32. 2-methyl-4-isothiazolin-3-one [CAS 2682-20-4]. No more than 1 μg/dm^2 of this substance should be detected in the extract of the finished product.

4.5.2.33. Dodecylguanidine hydrochloride [CAS 13590-97-1]. Maximum limit 0.02% in the formulation on dry fiber basis.

4.5.2.34. Stabilized hypobromite alkaline solution. Maximum limit 0.07% in the formulation on dry fiber basis. Maximum 10% sodium hypobromite and 12% sodium sulfamate [CAS 13845-18-6] in the solution.

4.5.2.35. 1,3-dimethol-5,5-dimethylhydantoin [CAS 6440-58-0]. Maximum limit 0.04% in the formulation on dry fiber basis.

4.5.2.36. Chlorine dioxide.

4.5.2.37. Tetrahydro-1,3,4,6-tetrakis-(hydroxymethyl) imidazo [4,5-d] imidazole-2,5 (1H, 3H)-dione [CAS 5395-50-6] as a formaldehyde donor system with an average ratio for formaldehyde to acetylene diurea between 3.1:1 and 3.5:1. No more than

0.3 mg/dm^2 (corresponding to formaldehyde 0.1 mg/dm^2) should be detected in the extract of the finished product.

4.5.2.38. Sodium hypochlorite. Maximum limit 0.028% in the formulation on dry fiber basis. For the stabilization of sodium hypochlorite, 0.05% of 5,5-dimethylhydantoin can be used in the form of sodium salt in relation to the dry fiber.

4.5.2.39. N,N'-dihydroxymethylene urea. Maximum limit 0.0125% dry fiber basis. No more than 1.0 mg/dm^2 of formaldehyde should be detected in the extract of the finished product.

4.5.2.40. 1,6-dihydroxy-2,5-dioxahexane. Maximum limit 0.029% on dry fiber basis. No more than 1.0 mg/dm^2 of formaldehyde should be detected in the extract of the finished product.

4.5.2.41. Sodium xylenesulfonate [CAS 1300-72-7]. Maximum limit 0.01% in the finished product.

4.5.2.42. Propylene glycol methyl ether [CAS 107-98-2] and dipropylene glycol methyl ether [CAS 34590-94-8], only for use in contact with non-fatty dry solid food.

4.5.2.43. C12-C18 alkyl dimethyl benzyl ammonium chloride.

4.5.2.44. 2-octyl-2H-isothiazol-3-one [CAS 64359-81-5], the extract content of the finished product should not exceed 5μg/dm^2.

4.6. Preservatives

The preservatives listed in 4.6.1 to 4.6.14 shall be used only in the quantities needed to protect the raw materials, production aids and finishing agents of the packaging from deterioration and shall not act as a preservative for the food.

4.6.1. Sorbic acid [CAS 110-44-1].

4.6.2. Formic acid [CAS 64-18-6] and sodium formate [CAS 141-53-7].

4.6.3. Aqueous solution of 0.15% p-hydroxybenzoic acid esters (methyl esters [CAS 99-76-3], ethyl esters [CAS 120-47-8] and n-propyl esters [CAS 94-13-3] as well as their sodium salts) in hydrogen peroxide (35% (m/m)). Maximum limit 15 mg of ester per kg of finished product and should not act as a preservative for the food. No peroxides should be detected in the extract of the finished product.

4.6.4. Benzoic acid [CAS 65-85-0].

4.6.5. Compound of 70% benzyl alcohol [CAS 100-51-6] and 30% formaldehyde. No more than 1.0 mg/dm^2 of formaldehyde should be detected in the extract of the finished product.

4.6.6. Barium metaborate [CAS 26124-86-7]. Only for coating and surface gluing of papers, paperboards and cartons in contact with dry foods.

4.6.7. Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one (about 3 parts) and 2-methyl-4-isothiazolin-3-one (approx 1 part). No more than 0.5 μg/dm^2 of isothiazolinones should be detected in the extract of the finished product.

4.6.8. Methylene bis (thiocyanate) [CAS 6317-18-6]. This auxiliary substance should not be detected in the extract of the finished product.

4.6.9. o-phenyl phenol [CAS 90-43-7] and its sodium and potassium salts. Maximum limit 0.01% on dry fiber basis.

4.6.10. Sodium tetraborate. Maximum limit 0.005% in the formulation on dry fiber basis.

4.6.11. 2-methyl-4-isothiazolin-3-one. No more than 1.0 μg/dm^2 of isothiazolinone should be detected in the extract of the finished product.

4.6.12. 1,2-benzisothiazolin-3-one. No more than 10.0 μg/dm^2 of isothiazolinone should be detected in the extract of the finished product.

4.6.13. Zinc piritonato. Maximum limit 17 μg/dm^2 of finished product.

4.6.14. N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine. No more than 10 μg/dm^2 of this substance should be detected in the extract of the finished product.

4.7. Stabilizing agents (precipitants), fixing agents, parchment-dressing agents and the others not classified in items 4.1 to 4.6

4.7.1. Hydrated aluminum sulphate [CAS 17927-65-0] and anhydrous aluminum sulphate [CAS 10043-01-3].

4.7.2. Sulfuric acid [CAS 7664-93-9].

4.7.3. Aluminum formate [CAS 7360-53-4].

4.7.4. Aluminum oxychloride.

4.7.5. Sodium aluminate.

4.7.6. Tannin.

4.7.7. Condensation products of urea, dicyandiamide [CAS 461-58-5] and melamine with formaldehyde. The aqueous extract of the finished product must not contain more than 1.0 mg/dm^2 of formaldehyde.

4.7.8. Condensation products of aromatic sulphonic acids with formaldehyde. Maximum limit 1.0% dry fiber basis. The aqueous extract of the finished product must not contain more than 1.0 mg/dm^2 of formaldehyde.

4.7.9. Sodium salts of ethylenediaminetetraacetic acid [CAS 6381-92-6], diethylenetriaminepentaacetic acid and N-hydroxyethyl ethylenediaminetriacetic acid.

4.7.10. Carbonate [CAS 497-19-8], bicarbonate [CAS 144-55-8] and sodium phosphate [CAS 7601-54-9].

4.7.11. Carbon dioxide (carbon dioxide).

4.7.12. Sodium hydroxide [CAS 1310-73-2].

4.7.13. Gluconic acid [CAS 526-95-4].

4.7.14. Ammonium hydroxide.

4.7.15. Copolymer of vinylformamide-vinylamine. Maximum limit 0.4% dry fiber basis.

4.7.16. Polycondensate of dicyandiamide and diethylenetriamine. Maximum limit 0.45% dry fiber basis.

4.7.17. Polyethylenimine, modified with polyethylene glycol and epichlorohydrin. Maximum limit 0.2% dry fiber basis.

4.7.18. 2-Hydroxy-N,N,N-trimethylethanaminium [CAS 62-49-7] and its salts.

4.7.19. Copolymer of vinylformamide, vinylamine and acrylic acid. Maximum limit 1% in the formulation on dry fiber basis.

4.7.20. Disodium phosphate [CAS 7558-79-4].

4.7.21. Sodium glucoheptanoate [CAS 13007-85-7], to be used as a processing aid (chelating agent). The amount of that substance should not exceed the amount needed to accomplish the desired technical effect.

4.7.23. Hydrochloric acid [CAS 7647-01-0]. The added amount of this substance should not exceed the amount needed to accomplish the desired technical effect.

4.7.24. Glucose [CAS 50-99-7].

5. SPECIAL AIDS FOR PAPER

5.1. Agents improving mechanical properties of wet strength

5.1.1. Glyoxal. The extract of the finished product must contain at most 1.5 mg/dm^2 of glyoxal.

5.1.2. Urea-formaldehyde resin. In the extract of the finished product no more than 1.0 mg/dm^2 of formaldehyde should be detected.

5.1.3. Melamine-formaldehyde resin. In the extract of the finished product no more than 1.0 mg/dm^2 of formaldehyde should be detected.

5.1.4. Crosslinked cationic polyalkyleneamines. Maximum limit in total 4.0% (m/m) dry fiber basis of the set of additives formed by items a, b, c, d, e, f, g, h, i and j.

a) Polyamine-epichlorohydrin resin synthesized from epichlorohydrin and diaminopropylmethylamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

b) Polyamide-epichlorohydrin resin synthesized from epichlorohydrin, adipic acid, caprolactam, diethylenetriamine and / or ethylenediamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

c) Polyamide-epichlorohydrin resin synthesized from adipic acid, diethylenetriamine and epichlorohydrin and a mixture of epichlorohydrin and ammonium hydroxide. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

d) Polyamide-polyamine-epichlorohydrin resin synthesized from epichlorohydrin, adipic acid dimethyl ester and diethylenetriamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

e) Polyamide-polyamine-epichlorohydrin resin synthesized from epichlorohydrin, an adipic acid amide and diaminopropylmethylamine. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

f) Polyamide-epichlorohydrin resin, obtained from epichlorohydrin, diethylenetriamine, adipic acid, ethyleneimine and polyethylene glycol. Maximum limit 0.2% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

g) Polyamide-epichlorohydrin resin, obtained from bis-(3-aminopropyl) methylamine, adipic acid and epichlorohydrin. Maximum limit 1.0% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

h) Polyamide-epichlorohydrin resin obtained from bis- (3-aminopropyl) methylamine, epichlorohydrin, urea and oxalic acid [CAS 144-62-7]. Maximum limit 1.0% dry fiber basis. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

i) Polyamide-epichlorohydrin resin obtained from diethylenetriamine, adipic acid, glutaric acid [CAS 110-94-1], succinic acid [CAS 110-15-6] and epichlorohydrin. They should not be detected in the aqueous extract of the finished product:

epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

j) Polyamide-epichlorohydrin resin, obtained from diethylenetriamine, triethylenetetramine, adipic acid and epichlorohydrin. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

5.1.5. Vinylformamide-vinylamine copolymer. Maximum limit 1.0% dry fiber basis.

5.1.6. Polyhexamethylene-1,6-diisocyanate modified with polyethylene glycol monoethyl ether. Maximum limit 1.2% dry fiber basis.

5.1.7. Polyhexamethylene-1,6-diisocyanate modified with polyethylene glycol monoethyl ether and N,N-dimethylaminoethanol. Maximum limit 1.2% dry fiber basis.

5.1.8. Acrylamide terpolymer, diallyldimethyl ammonium chloride [CAS 7398-69-8] and glyoxal. Maximum limit 2% in the formulation dry fiber basis. Maximum limit 1.5 mg of glyoxal/dm^2 in the extract of the finished product.

5.1.9. Copolymer of hexamethylenediamine [CAS 124-09-4] and epichlorohydrin. Maximum limit 2.0% based on dry fiber. They should not be detected in the aqueous extract of the finished product: epichlorohydrin (limit of detection: 1 mg/kg) and 1,3-dichloro-2-propanol (limit of detection: 2 µg/l). No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

5.1.10. Copolymer of diethylenetriamine, adipic acid, 2-aminoethanol and epichlorohydrin. Maximum limit 0.1% in the dry fiber base formulation. No ethylenimine should be detected in the resin (detection limit: 0.1 mg/kg). 1,3-dichloro-2-propanol (limit of detection: 2 µg/l) and epichlorohydrin (detection limit: 1 mg/kg) should not be detected in the finished product extract. The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

5.1.11. Copolymer of diethylenetriamine, adipic acid, acetic acid [CAS 64-19-7] and epichlorohydrin. Maximum limit 2% in the formulation dry fiber basis. This copolymer should only be used in the manufacture of tissue papers for use in

culinary operations. No ethylenimine should be detected in the resin (detection limit: 0.1mg/kg). 1,3-dichloro-2-propanol (limit of detection: 2 µg/l) and epichlorohydrin (detection limit: 1 mg/kg) should not be detected in the finished product extract. The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

5.1.12. Copolymer of vinylformamide and acrylic acid. Maximum limit 1% in the formulation dry fiber basis.

5.1.13. Formamide derivatives, hydrolyzed N-ethenyl homopolymer, N-(3-carboxy-1-oxopropyl) N-(2-hydroxy-3-trimethylammonium)-propyl [CAS 945630-11-5] chlorides. Limit maximum 0.4% on dry fiber basis.

5.2. Moisture Retention Agents

The additives described in 5.2.1 to 5.2.11 may be used provided that the summatory of the substances does not exceed 7% in relation to the finished product.

5.2.1. Glycerin [CAS 56-81-5].

5.2.2. Sorbitol [CAS 50-70-4].

5.2.3. Sucrose [CAS 57-50-1], glucose, glucose syrup, invert sugar syrup.

5.2.4. Sodium Chloride [CAS 7647-14-5], Calcium Chloride [CAS 10035-04-8].

5.2.5. Polyethylene glycol: with a maximum of 0,2% (m/m) of monoethylene glycol.

5.2.6. Urea.

5.2.7. Sodium nitrate [CAS 7631-99-4], only in combination with urea.

5.2.8. Polypropylene glycol (minimum molecular mass 1000 Dalton).

5.2.9. Propylene glycol [CAS 57-55-6].

5.2.10. Sodium dioctylsulfosuccinate.

5.2.11. Dipropylene Glycol [CAS 25265-71-8].

5.3. Pigments, colorants and optical brighteners

5.3.1. Pigments and colorants should not migrate into food according to the methodology referred to in item 2.15 of the General Provisions.

5.3.2. For optical brighteners, the migration test must be carried out according to the methodology referred to in item 2.16 of the General Provisions, and the grade 5 (five) must be reached in the methodology evaluation scale.

5.3.3. Sulfonated stilbene derivatives may be added in the mass or at the surface. Maximum limit 0.3% in relation to the finished product.

5.3.4. The purity criteria for colorants and pigments are:
a) Antimony (Sb) soluble in 0.1N HCl: maximum 0,05% (m/m);
b) Arsenic (As) soluble in 0.1N HCl: maximum 0.005% (m/m);
c) Barium (Ba) soluble in 0.1N HCl: maximum 0,01% (m/m);
d) Cadmium (Cd) soluble in 0.1N HCl: maximum 0,01% (m/m);
e) Chromium (Cr) soluble in 0.1 N HCl: maximum 0.10% (m/m);
f) Mercury (Hg) soluble in 0.1N HCl: maximum 0.005% (m/m);
g) lead (Pb) soluble in 0.1N HCl: maximum 0,01% (m/m);
h) Selenium (Se) soluble in 0.1N HCl: maximum 0,01% (m/m);
i) Zinc (Zn) soluble in 0.1 N HCl: maximum 0.20% (m/m).

The purity criteria foreseen in this item should be evaluated according to the analytical methodology described in the Technical Regulation MERCOSUR on Colorants in Packaging and Plastic Equipment intended to be come contact with food.

5.3.5. Aromatic amines should not be detected (limit of detection: 0.1 mg/kg of paper).

5.3.6. Azo dyes should not release one or more of the aromatic amines listed in the table below, by reducing fragmentation of one or more azo groups (limit of detection: 0.1 mg/kg paper):

CAS Number	Substance	
92-67-1	Biphenyl-4-ylamine 4-aminobiphenyl Xenylamine	
92-87-5	Benzidene	
95-69-2	4-chloro-o-toluidine	
91-59-8	2-naphthylamine	
97-56-3	o-aminoazotoluene 4-amino-2 ', 3-dimethylazobenzene 4-o-tolylazo-o-toluidine	

99-55-8	5-nitro-o-toluidine	
106-47-8	4-chloroaniline	
615-05-4	4-methoxy-m-phenylenediamine	
101-77-9	4,4'-methylenedianiline 4,4'-diamindiphenylmethane	
91-94-1	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediaminene	
119-90-4	3,3'-dimethoxybenzidine o-dianisidine	
119-93-7	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	
838-88-0	4,4'-methylene-o-toluidine	
120-71-8	6-methoxy-m-toluidine p-cresidine	
101-14-4	4,4'-methylene-bis- (2-chloroaniline) 2,2'-dichloro-4,4'-methylenedianiline	
101-80-4	4,4'-oxyaniline	
139-65-1	4,4'-thiadiapane	
95-53-4	o-toluidine 2-aminotoluene 2-methylaniline	
95-80-7	4-methyl-m-phenylenediamine 4-methylbenzene-1,3-diamine	
137-17-7	2,4,5-trimethylaniline	
90-04-0	o-anisidine 2-	

	methoxyaniline	
60-09-3	4-aminoazobenzene	

5.4. Coating and surface-active agents

5.4.1. Plastic materials (in the form of films, solutions, dispersions or for extrusion coating) that comply with the MERCOSUR Technical Regulations on Packaging and Plastic Equipment in Contact with Foods.

5.4.2. Paraffins, microcrystalline waxes, polyolefins and low molecular weight polyterpenes: must comply with the MERCOSUR Technical Regulation on Food Contact Paraffins.

5.4.3. Polyvinyl alcohol: viscosity of the aqueous solution 4% (m/m) at 20°C, not less than 5 mPa-s.

5.4.4. Chromium trichloride complexes with saturated fatty acids of linear chain of C14 and higher. Limit maximum 0.4 mg/dm^2 expressed in chromium. The aqueous cold extract of the finished product should not contain more than 0.004 mg/dm^2 of trivalent chromium and no hexavalent chromium should be detected.

5.4.5. Fatty acids (C12 to C20) salts of ammonium, aluminum, calcium, potassium and sodium. For calcium stearate [CAS 1592-23-0], the use of n-decanol [CAS 112-30-1] as a stabilizing agent for the dispersion is permitted. The substances provided for in this item must comply with the purity requirements of food additives.

5.4.6. Casein and vegetable proteins. The sum of the impurities (arsenic, lead, mercury and cadmium) must not exceed 50 mg/kg. These requirements apply only to agents for surface improvement and coating. In the event that these agents are related to other properties already mentioned above, consider the requirements established there.

5.4.7. Starch: All starches mentioned in 4.1.3 must comply with the specifications established therein.

5.4.8. Manogalactans and galactomannan ethers. These substances may contain the pollutants listed below, within the maximum limits established: arsenic: 3 mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and Copper combined: 50 mg/kg. The sum of the said impurities must be less than 50 mg/kg. Galactomannan ethers should not contain more than 0.5% sodium glycollate, 1 mg/kg epichlorohydrin and 4% nitrogen.

5.4.9. Sodium salt of pure carboxymethylcellulose [CAS 9004-32-4]. This substance may contain the following contaminants within the maximum limits: Arsenic: 3

mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and Copper combined: 50 mg/kg. The sum of the said impurities must be less than 50 mg/kg. Sodium glycollate: maximum 0.5% (m/m). These requirements apply only to agents for surface improvement and coating. In case these agents are related to other properties, consider the requirements established there.

5.4.10. Methylcellulose [CAS 9004-67-5]. This substance may contain the following contaminants, within the established limits: Arsenic: 3 mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and copper combined: 50 mg/kg. The sum of the said impurities must be less than 50 mg/kg.

5.4.11. Hydroxyethylcellulose [CAS 9004-62-0]. This substance may contain the following contaminants within the maximum limits: Arsenic: 3 mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and copper combined: 50 mg/kg. The sum of the said impurities must be less than 50 mg/kg.

5.4.12. Alginates. This substance may contain the following contaminants within the maximum limits: Arsenic: 3 mg/kg; Lead: 10 mg/kg; Mercury: 2 mg/kg; Cadmium: 2 mg/kg; Zinc: 25 mg/kg; Zinc and copper added: 50 mg/kg. The sum of the said impurities must be less than 50 mg/kg.

5.4.13. Xanthan gum [CAS 11138-66-2]. Must comply with the MERCOSUR Technical Regulations on food additives.

5.4.14. Natural and synthetic mineral substances insoluble in water and harmless to health according to items 3.1 to 3.9. of PART II.

5.4.15. Dimethyl, isopropyl, isopropyl methyl, methyl 1-methyl-C9-C49-alkyl siloxanes (silicones) [CAS 144635-08-5]. Only for use as components of coatings made with polyolefins provided in the Technical Regulation MERCOSUR on Positive List of Monomers, other Starting Substances and Authorized Polymers for the Production of Packaging and Plastic Equipment in Contact with Food. Max. 3% by weight of the coating composition. Cellulosic materials using these coatings may be in contact with aqueous foods containing up to 8% alcohol, under pasteurization or hot filling conditions up to 94°C.

5.4.16 Polysiloxanes obtained from the reaction with platinum catalyst of: dimethyl polysiloxane with terminal vinyl groups [CAS 68083-19-2 and CAS 68083-18-1] and methyl hydrogen polysiloxane [CAS 63148-57-2] or Dimethyl methyl hydrogen polysiloxane [CAS 68037-59-2]. Polymerization inhibitors: diallyl maleate [CAS 999-21-3], 1-ethynyl-1-cyclohexanol [CAS 78-27-3] and vinyl acetate [CAS 108-05-4] may be used. The platinum content should not exceed 200 mg/kg. It can only be used for the following applications: contact with acid and non-acid aqueous food, beverages and moist bakery products without oil or fats on the surface at room temperature or below; or contact with acid and non-acid aqueous food containing oils or fats (including water-in-oil emulsions), modified or non-modified dairy

products (oil-in-water and water-in-oil emulsions), low moisture fatty products, moist bakery products with oil or fats on the surface and dry solids with or without oil or fats on the surface at temperatures below 121°C and not irradiated.

5.4.17. Ammonium carbonate and zirconium [CAS 32535-84-5]. Maximum limit 1.0 mg/dm^2 (expressed as zirconium dioxide, ZrO_2).

5.4.18. Copolymer of vinyl alcohol and isopropenyl alcohol. Viscosity of aqueous solution 4% (m/m) at 20°C, not less than 5 mPa-s.

5.4.19. Potassium carbonate and zirconium [CAS 23570-56-1]. Maximum limit 1.25 mg/dm^2 (expressed as zirconium dioxide, ZrO_2).

5.4.20. Dimethyl ammonium chloride of dihydrogenated fatty fatty acid 2-hydroxyethyl ester. Maximum limit 0.06% on dry fiber basis.

5.4.21. Imidazole compounds, 2-(C17- and C17-unsaturated alkyl) -l-[2- (C18- and C18-unsaturated) ethyl]-4,5-dihydro-1-methyl methylsulfates [CAS 72749-55-4] Or imidazole compounds, 2- (C17- and C17-unsaturated alkyl)-1-[2-(C18- and C18-unsaturated amido) ethyl]-4,5-dihydro-1-ethyl ethylsulfates. Maximum limit 0.5% in the formulation dry fiber basis.

5.4.22. Ethoxylated perfluoropolyetherdiol phosphoric acid esters. Maximum limit 1.5% in the formulation dry fiber basis.

5.4.23. Polyethylene terephthalates, modified from polyethylene terephthalate and one or more of the following substances or classes of substances: ethylene glycol, trimethylolpropane [CAS 77-99-6], pentaerythritol [CAS 115-77-5], C16-22 fatty acids and their Triglycerides, isophthalic acid [CAS 121-91-5] and trimellitic anhydride [CAS 552-30-7]. Maximum limit $0.1g/dm^2$.

5.4.24. Copolymer of 2-methyl-2-(dimethylamino) ethyl acrylate and γ-, ω-perfluoro-(C8-C14) alkyl acrylate, n-oxide, acetate. Maximum limit 5 mg/dm^2.

5.4.25. Copolymer of 2-methyl-2-(dimethylamino) ethyl acrylate and γ-, ω-perfluoro-(C8-C14) alkyl acrylate, n-oxide. Maximum limit 3.8 mg/dm^2.

5.4.26. Ammonium salt of perfluoropolyetherdicarbonic acid. Maximum limit 0.5%, in the formulation on dry fiber basis. Papers treated with this coating agent should not come into contact with aqueous and alcoholic foods.

5.4.27. Acetic copolymer and/or malate of 2-diethylaminoethyl methacrylate, 2,2'-ethylenedioxydiethyldimethacrylate, 2-hydroxyethylmethacrylate and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate . Maximum limit 1.2%, in the formulation dry fiber basis.

5.4.28. 2-Propenoic acid, 2-methyl-, polymer with 2-(diethylamino) ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate having a fluorine content of 45.1%. Maximum limit 0.6% in the formulation on dry fiber basis.

5.4.29. Reaction product between hexamethylene-1,6-diisocyanate (homopolymer) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol with a maximum content of Fluorine 48%. Maximum limit 0.16% on dry fiber basis.

5.4.30. Reaction products of 2-propen-1-ol with 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodiohexane, dehydroiodinate, reaction products with Epichlorohydrin and triethylenetetramine with a fluorine content of 54%. Maximum limit 0.5% dry fiber basis.

The 1,3-dichloro-2-propanol (detection limit 2 µg/l) should not be detected in the aqueous extract of the finished product. No ethylenimine should be detected in the resin (limit of detection 0.1 mg/kg). Epichlorohydrin (detection limit: 1 mg/kg) should not be detected. The transfer of 3-chloro-1,2-propanediol to the aqueous extract of the finished product should be as low as technically possible, and the limit of 12 µg/l should not be exceeded.

5.4.31. Copolymer of acrylic acid, methacrylate acid and sodium salt of polyethylene glycol methylethermonium methacrylate. Maximum limit 2.6 mg/dm^2.

5.4.32. Copolymer of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate, 2-hydroxyethyl acrylate, polyethylene glycol monoacrylate and polyethylene glycol diacrylate with a maximum fluorine content of 35.4%. Maximum limit 0.4% dry fiber basis.

5.4.33. Copolymer of methacrylic acid [CAS 79-41-4], 2-hydroxyethylmethacrylate [CAS 868-77-9], polyethylene glycol monoacrylate [CAS 26403-58-7] and sodium salt of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate with a maximum fluorine content of 45.1%. Maximum limit 0.8% on dry fiber basis.

5.4.34. Copolymer, in the form of acetate, methacrylic acid, 2-dimethylaminomethacrylate and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate, with a maximum fluorine content of 44.8%. Maximum limit 0.6% on dry fiber basis.

5.4.35. Poly- (oxyhexafluoropropylene), polymer with 3-N-methylaminopropylamine, N, N-dimethyldipropylenetriamine and poly (hexamethylene diisocyanate), with a maximum fluorine content of 59.1%. Maximum limit 4 mg/dm^2.

5.4.36. Coating system consisting of (from outside to inside): poly (vinyl alcohol) with bentonite in unmodified sodium form (minimum layer thickness 1 µm), linear low density polyethylene (minimum layer thickness 13 µm) and a metallized

polyethylene layer (minimum layer thickness 14.9 μm). A maximum of 10% of bentonite may be used, based on the mass of poly(vinyl alcohol).

5.4.37. Copolymer of 2-methylaminoethyl methacrylate and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate acetate, N-oxide, with a maximum fluorine content of 45% . Maximum limit 4 mg/dm^2.

5.4.38. Oxidized polyethylene waxes. Maximum limit 10 mg/dm^2 in the finished product.

5.4.39. Copolymer of dimethyl terephthalate, ethylene glycol, propane-1,2-diol, pentaerythritol, polyethylene glycol and polyethylene glycol monomethyl ether with 24% terephthalic acid. Maximum 0.05 mg/dm^2.

PART III

TESTS OF TOTAL AND SPECIFIC MIGRATION OF CELLULOSIC MATERIALS, PACKAGING AND EQUIPMENT INTENDED TO BE COME CONTACT WITH FOOD

1. SCOPE

1.1. This method is based on the gravimetric quantification of the total residue extracted from the cellulosic material after contact with food simulants under the intended conditions of use for cellulosic materials, packaging and equipment.

1.2. The following definitions are considered for the total migration tests:

1.2.1. Elaboration: conditions that are verified for relatively short periods, such as: pasteurization, sterilization, hot conditioning, etc .;

1.2.2. Fraction: operations through which parts of a food are divided and conditioned in containers of smaller volume, without changing its original composition;

1.2.3. Storage: prolonged contact during the shelf life of the product at temperatures between freezing to ambient or higher;

1.2.4. Distribution: supply or transport of products from points of production to points of sale, use or consumption;

1.2.5. Marketing: act of selling or buying goods; Y

1.2.6. Consumption: ingestion in the packaging or utensil, with or without food heating.

2. EXTRACTION CONDITIONS FOR DETERMINING TOTAL MIGRATION

2.1. The contact of the cellulosic materials with the simulants, under the selected time and temperature conditions, shall be carried out in such a way as to reproduce or represent the normal and foreseeable conditions of use in the processing, fractionation, storage, distribution, commercialization and food consumption.

2.2. Analyzes should be done in triplicate and there should be a blank test.

2.3. If a container or equipment of cellulosic material is used successively under various contact conditions, the migration tests shall be carried out by subjecting the same samples successively to these test conditions, using the same simulant.

2.4. For a given contact time, if the cellulosic material meets the limits in the migration tests at a specific temperature, it is not necessary to test at temperatures lower than this.

2.5. For a given contact temperature, if the cellulosic material meets the limits in the migration tests for a specific time, it is not necessary to test for shorter times to this.

2.6. When none of the contact conditions established in TABLE 1 of this Regulation apply, the conditions that best represent the use of the material, packaging or equipment should be used.

3. DETERMINATION OF TOTAL MIGRATION

3.1. REAGENTS

3.1.1. Distilled or deionized water of conductivity less than 2.5 µS/cm at 25°C.

3.1.2. Solution of 3% acetic acid (m/v), prepared from acetic acid diluted with distilled or deionized water of conductivity of less than 2.5 µS/cm at 25°C.

3.1.3. 10% (v/v) ethyl alcohol solution, prepared from 95% ethyl alcohol diluted with distilled or deionized water of conductivity below 2.5 µS/cm at 25°C.

3.1.4 n-heptane P.A.

3.2. GLASS MATERIAL AND EQUIPMENT

a) Distillation flasks;
b) Erlenmeyers;
c) Graduated cylinders;
d) Graduated pipettes;
e) Glass beads;
f) Porcelain capsules;
g) Beakers;
h) Desiccator;
i) Heating blanket;
j) Water bath with temperature controller;
k) Solvent distillation system;
l) Analytical balance, with a sensitivity of 0.1mg;
m) Rule calibrated, with the value of the smallest division of 1 mm.

Note: Both porcelain capsules and glassware used should not have worn surfaces, they should have been properly washed with appropriate detergent (neutral or alkaline) and rinsed with distilled water. For tests to determine the specific migration of metals, the glass material should also be washed by immersion in a

bath with a solution of nitric acid in 20% (v/v) distilled water and rinsed with distilled water.

3.3. PROCEDURE

3.3.1. Uncoated papers.

a) Cut a number of samples of dimensions such that the surface to be analyzed is at least 600 cm^2. To calculate the surface, consider the two sides of the paper.

b) Place the samples in a beaker and add the selected simulant in a ratio of 0.3 ml/cm^2 of the analyzed surface and use temperature and contact time according to the chosen condition (see TABLE 1).

Note: If the paper absorbs the simulant completely, the amount of the simulant must be increased in order to have an excess simulant.

c) For aqueous simulants (water, 3% acetic acid solution (m/v) and 10% (v/v) ethyl alcohol solution), at the end of the contact period, quantitatively transfer the extract to another beaker and reduce the volume to about 50 ml. Quantitatively transfer the reduced volume of the beaker to a tared capsule (or beaker of smaller capacity) and evaporate the extract completely.

d) For the n-heptane simulant, at the end of the contact period, quantitatively transfer the extract to a pre-tared distillation flask with a few glass beads and connect the distillation flask to a distillation system to remove the solvent until there are few milliliters of solvent in the bottom of the distillation flask.

Notes:
(1) The volume used in the washing and transfer operations of the extracts should be noted and be the same in all parallel determinations. This should preferably not exceed 100 ml.

(2) If the paper gives off fibers, the extract must be filtered, before evaporation, through a sintered glass crucible or filter and filter paper of rapid filtration, free of ash (e.g. Whatman No 41 or Similary).

e) Bring the capsule (or beaker) or distillation flask with the evaporation residue to an oven at (105 ± 3)^oC for one hour. Then cool the vessel in a desiccator for 30 minutes and weigh it in an analytical balance with a precision of 0.1 mg. Repeat the last three operations (drying on stove, cooling in desiccator and weighing) until obtaining constant weight. Make an analytical blank using the same volume of simulant used in the wash and transfer test.

3.3.2. Coated paper.

a) Cut a number of samples of dimensions such that the surface to be analyzed is at least 600 cm^2.

b) Place the samples in specific devices so that only the surface that will come in contact with the food is in contact with the simulant.

c) Place the chosen simulant in a ratio of 0.3 ml/cm^2 of surface analyzed and use temperature and contact time chosen (see TABLE 1).

d) For aqueous simulants (water, 3% acetic acid solution (m/v) and 10% (v/v) ethyl alcohol solution) at the end of the contact period, quantitatively transfer the extract to another beaker and reduce the volume to about 50 ml. Quantitatively transfer the reduced volume of the beaker to a capsule (or beaker of smaller capacity) tared and evaporate the extract completely.

e) For the n-heptane simulant, at the end of the contact period, quantitatively transfer the extract to a pre-tared distillation flask with a few glass beads, and connect the distillation flask to a distillation system to remove the solvent until there are few Milliliters of solvent in the bottom of the distillation flask.

Note: The volume used in the washing and transfer operations of the extracts should be noted and be the same in all parallel determinations. This should preferably not exceed 100 ml.

f) Bring the capsule (or beaker) or distillation flask with the evaporation residue to an oven at (105 ± 3)°C for one hour. Then cool the vessel in a desiccator for 30 minutes and weigh it in an analytical balance with a precision of 0.1 mg. Repeat the last three operations (drying in stove, cooling in desiccator and weighing) until obtaining constant weight. Make an analytical blank using the same volume of simulant used in the wash and transfer test.

4. CALCULATIONS

Express the total migration (MT) in mg/dm^2 according to the formulas:

4.1. Calculation for aqueous simulants (water, 3% acetic acid solution (m/v) and 10% (v/v) ethyl alcohol solution):
MT = (R1-R2)/A
Where:
R1 = mass of the sample residue, in mg;
R2 = mass obtained in the blank, in mg; A = total area of contact with the simulant, in dm^2;
4.2. Calculation for the n-heptane simulant:
MT = (R1 -R2)/(A x n)

Where:
R1 = mass of the sample residue, in mg;
R2 = mass obtained in the blank, in mg;
A = total area of contact with the simulant, in dm^2;
N = The number "n" is the reduction factor of the simulant D, conventionally used to consider the higher extractive capacity of the simulant D in relation to the extractive capacity of the food in question. N = 5.

Notes:
a) If the residue (R1) of the first test is below the detection limit, repeat the determination using a larger area sample. A higher volume of simulant may be used if necessary.

b) Express as final result the average of the three determinations with an accuracy of 1 decimal, accompanied by its standard deviation.

5. DETERMINATION OF SPECIFIC MIGRATION

5.1. The specific migration of an element or substance with restriction in this Regulation is determined from the quantity of the element in the extract of the total migration.

5.2. For the calculation of the specific migration of elements or substances with restrictions in this Regulation, in mg/kg, the following formulas apply:
$ME = (m \times S)/(A \times M)$
Where:
ME: specific migration of substance or element per kilogram of feed expressed in mg/kg;
M: mass of substance or element in the extract of migration, expressed in mg;
A: total contact area of the sample with simulant, expressed in dm^2;
(S/M): relationship between the contact area of the cellulosic material (S) and the mass of food (M) expressed in dm^2/kg. When the mass of the food is not known, the mass of water corresponding to the volume of the package, expressed in kg, is used.

5.3. When the actual ratio (S/M) for a cellulosic material is not known, the ratio S/M = 6 dm^2/kg should be used.

TABLE 1 - CONDITIONS FOR MIGRATION TESTS

CONDITIONS OF CONTACT	CONDITION OF TEST			
	SIMULANT A Distilled water	SIMULANT B 3% acetic acid (m/v)	SIMULANT C 10% (v/v) ethanol (for foods with alcohol content between 5 and 10%) or equal to the concentration in the food (for foods with alcohol content> 10%)	SIMULANT D n-Heptane
A) Prolonged contact ➢Time (t): t > 24 h; and Temperature (T): T < 5°C ➢Time (t): t > 24 h; and Temperature (T): 5°C ≤ T< 40°C	20°C ± 1°C /48 h + 0.5h 50°C ± 2°C /24 h + 0.5h	20°C ± 1°C /48 h + 0.5h 50°C ± 2°C /24 h + 0.5h	20°C ± 1°C /48 h + 0.5h 50°C ± 2°C /24 h + 0.5h	20°C ± 1°C /30 min + 1min 20°C ± 1°C /30 min + 1min
B) Brief Contact ➢Time (t): 2 h ≤ t ≤ 24 h Temperature (T): ambient	40°C ± 1°C /24 h + 0.5h	40°C ± 1°C /24 h + 0.5h	40°C ± 1°C /24 h + 0.5h	20°C ± 1°C /15 min + 1min
C) Momentary Contact ➢Time (t): t < 2 h Temperature (T): ambient	40°C ± 1°C /2 h + 5min	40°C ± 1°C /2 h + 5min	40°C ± 1°C /2 h + 5min	20°C ± 1°C /15 min + 1min

D) Elaboración ➢Temperature (T): 40°C ≤ T < 80°C ➢Temperature (T): 80°C ≤ T ≤ 100°C ➢Temperature (T): T > 100°C	65°C ± 2°C /2 h + 5min 100°C ± 3°C /30 min + 1min 121°C ± 3°C /2 h + 5min	65°C ± 2°C /2 h + 5min 100°C ± 3°C /30 min + 1min 121°C ± 3°C /2 h + 5min	65°C ± 1°C /2 h + 5min Does not apply Does not apply	40°C ± 1°C /30 min + 1min 50°C ± 2°C /30 min + 1min 65°C ± 2°C /2 h + 5min
E) Hot Packing ➢Temperature (T): T > 70°C	Fill with the simulant at boiling T and cool to the temperature of the sequential test.	Fill with the simulant at boiling T and cool to the temperature of the sequential test.	Does not apply	50°C± 2°C /15 min+ 1min