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Title 21 - Food and Drugs

Chapter I —Food and Drug Administration, Department of Health and Human Services Subchapter B —Food for Human Consumption

Part 176 —Indirect Food Additives: Paper and Paperboard Components

Subpart B —Substances for Use Only as Components of Paper and Paperboard

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

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§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section.

Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of § 176.180.

- (a) Substances identified in paragraph (a)(1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.
 - (1) Substances generally recognized as safe in food.
 - (2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.
 - (3) Substances used in accordance with a prior sanction or approval.
 - (4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

List of Substances	Limitations
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 600 centipoises at 75 °F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m Acrylamide- β -methacrylyloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 10 molar percent of β -methacrylyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 0.05 percent by weight of dry fibers in the finished paper and paperboard. For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
monomer Acrylic acid, sodium salt copolymer with polyethyleneglycol allyl ether (CAS Reg. No. 86830-15-1)	For use only in paper mill boilers.
Acrylic acid copolymer with 2-acrylamido-2-methylpropane-sulfonic acid (CAS Reg. No. 40623-75-4) and/or its ammonium/alkali metal mixed salts. The copolymer is produced by poly- merization of acrylic acid and 2-acrylamido-2-methylpropane-sulfonic acid in a weight ratio of 60/40, such that a 28 percent by weight aqueous solution of the polymer has a viscosity of 75-150 centipoises at 25 °C as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 60 r.p.m	For use only as a scale inhibitor prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.0 kilogram (2.2 pounds) of copolymer per 907 kilograms (1 ton) of dry paper and paperboard fibers.
Acrylonitrile polymer, reaction product with ethylenediamine sulfate having a nitrogen content of 22.5-25.0 percent (Kjeldahl dry basis) and containing no more than 0.075 percent monomer as ethylenediamine. The finished resin in a 24 percent by weight aqueous solution has a viscosity of 1,000-2,000 centipoises at 25 °C as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 50 r.p.m. (or by other equivalent method)	For use only as a size promoter and retention aid at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
Acrylonitrile polymer with styrene, reaction product with ethylenediamine acetate, having a nitrogen content of 7.4-8.3 percent (Kjeldahl dry basis) and containing no more than 0.25 percent monomer as ethylenediamine	For use only as a sizing material applied after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in

List of Substances	Limitations
	excess of 0.25 percent by weight of the dry paper and paperboard. 2. For use only as a sizing material applied prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 1.0 percent by weight of the dry paper and paperboard.
1-Alkenyl olefins, containing not less than 72 percent of C_{30} and higher olefins	For use only under the following conditions: 1. In coatings for paper and paperboard with food of Types I, II, IV-B, and VII-B described in table 1 of paragraph (c) of this section under conditions of use E, F, and G described in table 2 of paragraph (c) of this section. 2. In coatings for paper and paperboard with food of Type VIII described in table I of paragraph (c) of this section under conditions of use A through H described in table 2 of paragraph (c) of this section.
(2-Alkenyl) succinic anhydrides mixture, in which the alkenyl groups are derived from olefins which contain not less than 95 percent of $C_{15}\text{-}C_{21}$ groups	For use only as a sizing agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished dry paper and paperboard fibers.
Alkyl(C ₁₂ -C ₂₀)methacrylatemethacrylic acid copolymers (CAS Reg. No. 27401-06-5)	For use only as stabilizers employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
tert-Alkyl(C ₈ -C ₁₆)mercaptans Aluminum acetate	For use only as polymerization-control agent.
2-Amino-2-methyl-1-propanol (CAS Reg. No. 124-68-5)	For use as a dispersant for pigment suspension at a level not to exceed 0.25 percent by weight of pigment. The suspension is used as a component of coatings for paper and paperboard under conditions of use described in paragraph (c) of this section, table 2, conditions of use E through G.
Ammonium persulfate	
Ammonium thiosulfate	
Ammonium zirconium carbonate (CAS Reg. No. 32535-84-5) and its tartaric acid adduct	For use only as an insolubilizer for binders used in coatings for paper and paperboard,

List of Substances Limitations and limited to use at a level not to exceed 2.5 percent by weight of coating solids. Ammonium zirconium citrate (CAS Reg. No. For use as insolubilizers with protein binders 149564-62-5), ammonium zirconium lactate-citrate (CAS in coatings for paper and paperboard, at a Reg. No. 149564-64-7), ammonium zirconium lactate level not to exceed 1.4 percent by weight of (CAS Reg. No. 149564-63-6) coating solids. Anionic polyurethane, produced by reacting the For use only as a surface sizing agent at a preliminary adduct formed from the reaction of glyceryl level not to exceed 0.1 percent by weight of monostearate and 2.4-toluenediisocvanate with not dry paper and paperboard. more than 10 mole percent N-methyldiethanolamine and not less than 90 mole percent dimethylolpropionic acid. The final product is a 15 to 20 percent by weight agueous solution, having a Brookfield viscosity of 25 to 100 centipoises at 24 °C (75 °F) 9,10-Anthraguinone (Chemical Abstracts Service For use only as a pulping aid in the alkaline Registry No. 84-65-1) which has a purity of not less than pulping of lignocellulosic material at levels not to exceed 0.1 percent by weight of the 98 percent raw lignocellulosic material. Aromatic petroleum hydrocarbon resin, hydrogenated For use only as modifiers in wax polymer (CAS Reg. No. 88526-47-0), produced by the catalytic blend coatings for paper and paperboard at a polymerization of aromatic substituted olefins from low level not to exceed 50 weight-percent of the boiling distillates of cracked petroleum stocks with a coating solids under conditions of use E, F, boiling point no greater than 220 °C (428 °F), and the and G identified in table 2 of paragraph (c) of subsequent catalytic reduction of the resulting aromatic this section. petroleum hydrocarbon resin. The resin meets the following specifications: softening point 85 °C (185 °F) minimum, as determined by ASTM Method E 28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," and aniline point 70 °C (158 °F) minimum, as determined by ASTM Method D 611-82, "Standard Test Methods for Aniline Point and Mixed Aniline Point of Petroleum Products and

availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Azo-bisisobutyronitrile

For use o

Hydrocarbon Solvents," which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records

Administration (NARA). For information on the

1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)

For use only as polymerization catalyst. For use only as a preservative in paper

List of Substances	Limitations
	coating compositions and limited to use at a level not to exceed 0.01 mg/in ² (0.0016 mg/cm ²) of the finished paper and paperboard.
Benzoyl peroxide	Do.
<i>N,N</i> -Bis(2-hydroxyethyl)alkyl (C ₁₂ -C ₁₈)amide	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet forming operation.
Bis(methoxymethyl)tetrakis-[(octadecyloxy)-methyl]melamine resins having a 5.8-6.5 percent nitrogen content (CAS Reg. No. 68412-27-1)	For use only under the following conditions: 1. As a water repellant employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the finished paper and paperboard will contain the additive at a level not in excess of 1.6 percent by weight of the finished dry paper and paperboard fibers. 2. The finished paper and paperboard will be used in contact with nonalcoholic foods only. 3. As a water repellant employed after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the finished paper and paperboard will contain the additive at a level not to exceed 1.6 percent by weight of the finished dry paper and paperboard fibers. The finished paper and paperboard will be used only in contact with food of Types I, II, IV-B, VI, VII-B, and VIII described in table 1 of paragraph (c) of this section.
2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7)	For use only as an antimicrobial/preservative in fillers, pigment slurries, starch sizing solutions, and latex coatings at levels not to exceed 0.01 percent by weight of those components.
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.
tert-Butyl hydroperoxide	For use only as polymerization catalyst.
tert-Butyl peroxide	Do.
Calcium isostearate	For use only with <i>n</i> -decyl alcohol as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and

List of Substances	Limitations
	paperboard.
Carrageenan and salts of carrageenan as described in §§ 172.620 and 172.626 of this chapter	
Castor oil, hydrogenated	
Castor oil, sulfated, ammonium, potassium, or sodium salt	
Cellulose, regenerated	
Chloracetamide	For use only as polymerization-control agent.
Cobaltous acetate	For use only as polymerization catalyst.
Cumene hydroperoxide	Do.
Cyanoguanidine	For use only: 1. As a modifier for amino resins. 2. As a fluidizing agent in starch and protein coatings for paper and paperboard.
n-Decyl alcohol	For use only with calcium isostearate as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and paperboard.
Dialdehyde guar gum	For use only as a wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of the finished dry paper and paperboard fibers.
Dialdehyde locust bean gum	Do.
Dialkyl(C ₁₆ -C ₁₈)carbamoyl chloride (CAS Reg. No. 41319-54-4) manufactured by the reaction of secondary amines derived from fatty acids of animal or vegetable sources with phosgene	For use as a sizing agent at a level not to exceed 0.2 percent by weight of the dry fiber.
Diallyldimethyl ammonium chloride polymer with acrylamide and potassium acrylate, produced by copolymerizing either (1) diallyldimethyl ammonium chloride and acrylamide in a weight ratio of 50/50, with 4.4 percent of the acrylamide subsequently hydrolyzed to potassium acrylate or (2) polymerized diallyldimethyl ammonium chloride, acrylamide and potassium acrylate (as acrylic acid) in a weight ratio of 50/47.8/2.2, respectively, so that the finished resin in a 1 percent by weight aqueous solution (active polymer) has a viscosity of more than 22 centipoises at 22 °C (72 °F) as determined by LVF series, Brookfield Viscometer using No. 1 spindle at 60 RPM (or by other equivalent method)	For use only as a retention and/or drainage aid employed prior to the sheet-forming operations in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.

(CAS Reg. No. 25136-75-8)

Diallyldimethylammonium chloride with acrylamide (CAS Reg. No. 26590-05-6). The copolymer is produced by copolymerizing diallyldimethylammonium chloride with acrylamide in a weight ratio of 50-50 so that the finished resin in a 1 percent by weight aqueous solution (active polymer) has a viscosity of more than 22 centipoises at 22 °C (71.6 °F), as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method)

Diallyldiethylammonium chloride polymer with acrylamide, and diallyldimethylammonium chloride, produced by copolymerizing acrylamide, diallyldiethylammonium chloride, and diallyldimethylammonium chloride, respectively, in the following weight ratios and having viscosities determined at 22 °C, by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method), as follows:

- 1. Weight ratio: 50-2.5-47.5. The finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises
- 2. Weight ratio: 25-2.5-72.5. The finished resin in a 0.20 percent by weight aqueous solution has a minimum viscosity of 20 centipoises
- 3. Weight ratio: 80-2.5-17.5. The finished resin in a 0.30 percent by weight aqueous solution has a minimum viscosity of 50 centipoises

Diallyldiethylammonium chloride polymer with acrylamide, potassium acrylate, and diallyldimethylammonium chloride. The polymer is produced by copolymerizing either: (1) acrylamide, diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 50-2.5-47.5, respectively, with 4.4 percent of the

Limitations

For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.

For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.

For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.075 percent by weight of the finished paper and paperboard.

For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.075 percent by weight of the finished paper and paperboard.

For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.

List of Substances	Limitations
acrylamide subsequently hydrolyzed to potassium acrylate, or (2) acrylamide, potassium acrylate (as acrylic acid), diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 47.8-2.2-2.5-47.5, so that the finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises at 22 °C, as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method)	
Diallyldimethylammonium chloride polymer with acrylamide, reaction product with glyoxal, produced by copolymerizing not less than 90 weight percent of acrylamide and not more than 10 weight percent of diallyldimethylammonium chloride, which is then cross-linked with not more than 30 weight percent of glyoxal, such that a 10 percent aqueous solution has a minimum viscosity of 25 centipoises at 25 °C as determined by Brookfield viscometer Model RVF, using a No. 1 spindle at 100 r.p.m	For use only as a dry and wet strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 2 percent by weight of the dry fibers in the finished paper and paperboard.
2,2-Dibromo-3-nitrilopropionamide (CAS Reg. No.10222-01-2).	For use as a preservative at a level not to exceed 100 parts per million in coating formulations and in component slurries and emulsions, used in the production of paper and paperboard and coatings for paper and paperboard.
2,5-Di- <i>tert</i> -butyl hydroquinone	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.
Diethanolamine	For use only: 1. As an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheetforming operation. 2.In paper mill boilers.
Diethyl(2-hydroxyethyl) methylammonium methyl sulfate, acrylate, polymer with acrylamide, chemical abstract service registry No. [26796-75-8] having 90-95 mole pct. acrylamide, a nitrogen content of not more than 19.7 pct. (Kjeldahl, dry basis), and a residual acrylamide monomer content of not more than 0.1 pct. The finished polymer in a 1 pct. by weight aqueous solution has a minimum viscosity of 900 centipoises at 25 °C as determined by LVT-series Brookfield viscometer	For use only as a retention aid and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.15 pct. by weight of finished dry paper and paperboard fibers.

List of Substances	Limitations
using a No. 2 spindle at 12 r.p.m. (or by equivalent method)	
Diethylenetriamine	For use only as a modifier for amino resins.
N,N-Diisopropanolamide of tallow fatty acids	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Dimethylamine-epichlorohydrin copolymer in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine and in which the ratio of total amine to epichlorohydrin does not exceed 1:1. The nitrogen content of the copolymer shall be 9.4 to 10.8 weight percent on a dry basis and a 10 percent by weight aqueous solution of the final product has a minimum viscosity of 5.0 centipoises at 25 °C, as determined by LVT-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method)	For use only: 1. As a retention aid employed before the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished paper and paperboard. 2. At the size press at a level not to exceed 0.017 percent by weight of the finished paper and paperboard.
N-[(Dimethylamino)methyl]-acrylamide polymer with acrylamide and styrene having a nitrogen content of not more than 16.9 percent and a residual acrylamide monomer content of not more than 0.2 percent on a dry basis	For use only as a dry-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of finished dry paper or paperboard fibers.
N,N'-Dioleoylethylenediamine	
Diphenylamine	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.
Dipropylene glycol	
Disodium salt of 1,4-dihydro-9,10-dihydroxyanthracene (CAS Reg. No. 73347-80-5)	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.
<i>N,N'</i> -Distearoylethylenediamine	
n-Dodecylguanidine acetate	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper

List of Substances	Limitations
	bags for contact with dry food of Type VIII described in table I of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
n-Dodecylguanidine hydrochloride	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper bags for contact with dry food of Type VIII described in table I of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
Fatty acids derived from animal and vegetable fats and oils and salts of such acids, single or mixed, as follows:	
Aluminum.	
Ammonium.	
Calcium.	
Magnesium.	
Potassium.	
Sodium.	
Zinc.	
Ferric chloride	
Ferrous ammonium sulfate	
Fish oil, hydrogenated	
Fish oil, hydrogenated, potassium salt	
Furcelleran and salts of furcelleran as described in §§ 172.655 and 172.660 of this chapter	
Glutaraldehyde (CAS Reg. No. 111-30-8)	For use only as an antimicrobial agent in pigment and filler slurries used in the manufacture of paper and paperboard at levels not to exceed 300 parts per million by weight of the slurry solids.
Glyceryl lactostearate	
Glyceryl mono-1,2-hydroxystearate	
Glyceryl monoricinoleate	
Guar gum modified by treatment with β -diethylaminoethyl chloride hydrochloride	For use only as a retention aid and/or drainage aid employed prior to the sheet-forming operation in the manufacture of

Guar gum modified by treatment with not more than 25 weight percent of 2,3-epoxypropyltri-methylammonium chloride such that the finished product has a maximum chlorine content of 4.5 percent, a maximum nitrogen content of 3.0 percent, and a minimum viscosity in 1-percent-by-weight aqueous solution of 1,000 centipoises at 77 °F, as determined by RV-series Brookfield viscometer (or equivalent) using a No. 3 spindle at 20 r.p.m

N,N,N',N',N",N"-Hexakis

(methoxymethyl)-1,3,5-triazine-2,4,6-triamine polymer with stearyl alcohol, α -octadecenyl-omega-hydroxypoly(oxy-1,2-ethanediyl), and alkyl (C20 +) alcohols (CAS Reg. No. 130328-24-4)

Hexamethylenetetramine

Hydroquinone and the monomethyl or monoethyl ethers of hydroquinone

Hydroxymethyl-5,5-dimethylhydantoin (CAS Reg. No. 27636-82-4), mixture with

1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (CAS Reg. No. 6440-58-0)

Hydroxypropyl guar gum having a minimum viscosity of 5,000 centipoises at 25 °C., as determined by RV-series Brookfield viscometer using a No. 4 spindle at 20 r.p.m. (or other suitable method) and using a test sample prepared by dissolving 5 grams of moisture-free hydroxypropyl guar gum in 495 milliliters of a 70 percent by weight aqueous propylene glycol solution 12-Hydroxystearic acid-polyethylene glycol block copolymers (CAS Reg. No. 70142-34-6) produced by the reaction of polyethylene glycol (minimum molecular

weight 200) with 12-hydroxystearic acid

Limitations

paper and paperboard.

For use only as a retention aid and/or internal size employed prior to the sheetforming operation in the manufacture of paper and paperboard, and limited to use at a level: (1) Not to exceed 0.15 percent by weight of the finished dry paper and paperboard fibers intended for use in contact with all types of foods, except (2) not to exceed 0.30 pct. by weight of the finished dried paper and paperboard fibers for use with nonalcoholic and nonfatty food of types identified under Types I, II, IV-B, VI-B, VII-B, and VIII of table I in par. (c) of this section. For use only as a water-repellent applied to the surface of paper and paperboard at levels not to exceed 1 percent by weight of the finished dry paperboard fibers. The finished paper and paperboard will be used in contact with aqueous foods under conditions of use B through G as described in table 2 of paragraph (c) of this section.

For use only as polymerization cross-linking agent for protein, including casein.

For use only as an inhibitor for monomers.

For use only as a preservative in clay-type fillers at a level not to exceed a combined total of 1,200 milligrams/kilograms hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin in the filler.

For use only as a dry strength and formation aid agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.5 percent by weight of finished dry paper or paperboard fibers.

For use only as a surfactant for dispersions of polyacrylamide retention and drainage aids employed prior to the sheet forming operation in the manufacture of paper and paperboard.

List of Cubatanasa	Limitations
List of Substances	Limitations
Imidazolium compounds, 2-(C ₁₇ and C ₁₇ -unsaturated alkyl)-1-[2-(C ₁₈ and C ₁₈ -unsaturated	For use only at a level not to exceed 0.5 percent by weight of the dry paper and
amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS	paperboard.
Reg. No. 72749-55-4).	paperboard.
Isopropyl <i>m</i> - and <i>p</i> -cresols (thymol derived)	For use only as an antioxidant for fatty based coating adjuvants provided it is used as a level not to exceed 0.005% by weight of coating solids.
Isopropyl peroxydicarbonate	For use only as polymerization catalyst.
Japan wax	
Lanolin	
Lauryl peroxide	For use only as polymerization catalyst.
Lauryl sulfate salts:	
Ammonium.	
Magnesium.	
Potassium.	
Sodium.	
Lecithin, hydroxylated	
Lignin sulfonate and its calcium, potassium, and sodium salts	
Maleic anhydride, polymer with ethyl acrylate and vinyl acetate, hydrolyzed (CAS Reg. No. 113221-69-5) and/or its ammonium, potassium, and sodium salts	For use only as a deposit control additive prior to the sheet forming operation to prevent scale buildup in the manufacture of paper and paperboard in contact with food, at a level not to exceed 0.075 percent (as the acid) by weight of the dry paper and paperboard.
Methacrylic acid-acrylic acid copolymer (CAS Reg. No. 25751-21-7)	For use only as a boiler water additive at a level not to exceed 50 parts per million in the boiler water.
N-methyldiallylamine hydrochloride polymer with epichlorohydrin having a nitrogen content of 4.8 to 5.9 percent (Kjeldahl dry basis) such that a 20 percent by weight aqueous solution has a minimum viscosity of 30 centipoises and maximum viscosity of 100 centipoises at 25 °C, as determined by LVF Model Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method)	For use only as a retention aid, flocculating agent, and wet-strength agent employed in the manufacture of paper and paperboard prior to the sheet-forming operation and limited to use at a level not to exceed 1.5 percent by weight of the dry paper and paperboard.
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.

List of Substances	Limitations
N-methyl-N-(tall oil acyl) taurine, sodium salt (CAS Reg. No. 61791-41-1)	For use only to control scale formation in the manufacture of paper and paperboard prior to the sheetforming operation at a level not to exceed 0.015 percent by weight of the dry paper and paperboard.
Mineral oil, white	
Mono-, di-, tri-(1-methyl-1-phenylethyl)-phenol, ethoxylated, sulfated, ammonium salt with an average of 12 to 16 moles of ethylene oxide (CAS Reg. No. 68130-71-2) Monoglyceride citrate	For use only as an emulsifier for rosin based sizing at a level not to exceed 0.03 percent by weight of the finished dry paper and paperboard.
Monoisopropanolamine (CAS Reg. No. 78-96-6)	For use as a dispersant for titanium dioxide suspensions at a level not to exceed 0.68 percent by weight of titanium dioxide. The finished paper and paperboard will be used in contact with all food types under conditions of use E through G described in table 2 of paragraph (c) of this section.
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Nitrocellulose, 10.9-12.2% nitrogen	
Oleic acid, sulfated, ammonium, potassium, or sodium salt	
N-Oleoyl-N'-stearoylethylenediamine	
Oxystearin	
Paraformaldehyde	For use only as setting agent for protein.
Petrolatum	Complying with § 178.3700 of this chapter.
Petroleum asphalt, steam and vacuum refined to meet the following specifications: Softening point 88 °C to 93 °C, as determined by ASTM method D36-76, "Standard Test Method for Softening Point of Bitumen (Ring-and-Ball Apparatus);" penetration at 25 °C not to exceed 0.3 mm, as determined by ASTM method D5-73 (Reapproved 1978), "Standard Test Method for Penetration of Bituminous Materials," which are incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National	For use only as a component of internal sizing of paper and paperboard intended for use in contact only with raw fruits, raw vegetables, and dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section, and provided that the asphalt is used at a level not to exceed 5% by weight of the finished dry paper and paperboard fibers.

List of Substances	Limitations
Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .); and maximum weight loss not to exceed 3% when distilled to 371 °C, nor to exceed an additional 1.1% when further distilled between 371 °C and thermal decomposition	
Petroleum wax, synthetic	Complying with § 178.3720 of this chapter.
Phenothiazine	For use only as antioxidant in dry rosin size.
Phenyl acid phosphate	For use only as polymerization catalyst in melamine-formaldehyde modified alkyd coatings and limited to use at a level not to exceed 2% by weight of the coating solids.
Phenyl-β-naphthylamine	For use only as antioxidant in dry rosin size and limited to use at a level not to exceed 0.4% by weight of the dry rosin size.
Phosphoric acid esters and polyesters (and their sodium salts) of triethanolamine formed by the reaction of triethanolamine with polyphosphoric acid to produce a mixture of esters having an average nitrogen content of 1.5 percent and an average phosphorus content of 32 percent (as PO ₄)	For use as an adjuvant prior to the sheet forming operation to control pitch and scale formation in the manufacture of paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under Types I, IV, V, VII, VIII, and IX, and used at a level not to exceed 0.075 percent by weight of dry paper or paperboard fibers.
Poly[acrylamide-acrylic acid- <i>N</i> -(dimethyl-aminomethyl)acryl-amide], produced by reacting 2.40 to 3.12 parts by weight of polyacrylamide with 1.55 parts dimethylamine and 1 part formaldehyde, and containing no more than 0.2 percent monomer as acrylamide	For use only as a drainage aid and retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard for use in contact with fatty foods under conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G.
Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) produced when one mole of hydroxypropyl acrylate and three moles of acrylic acid are reacted with three moles of ethylenimine and three moles of nitric acid, such that a 35 percent by weight aqueous solution has a minimum viscosity of 150 centipoises at 72 °F., as determined by RVF-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 20 r.p.m	For use only as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.2 percent by weight of dry paper or paperboard fiber.
Polyacrolein (1 part) -sodium bisulfite (0.7 part) adduct, containing excess bisulfite (ratio of excess bisulfite to adduct not to exceed 1.5 to 1)	For use only as an agent in modifying starches and starch gums used in the production of paper and paperboard and

Poly[acrylamide-acrylic acid-*N*-(dimethylaminomethyl) acrylamide] (C.A. Registry No. 53800-41-2), produced by reacting 9.6-16.4 parts by weight of polyacrylamide with 1.6 parts dimethylamine and 1 part formaldehyde, and containing no more than 0.2% monomer as acrylamide, such that a 20% aqueous solution has a minimum viscosity of 4,000 cP at 25 °C., as determined by Brookfield viscometer model RVT, using a No. 5 spindle at 20 r/min (or equivalent method)

Polyamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylene triamine to produce a basic polyamide which is modified by reaction with formic acid and formaldehyde and further reacted with epichlorohydrin in the presence of ammonium hydroxide to form a water-soluble cationic resin having a nitrogen content of 13-16 percent (Kjeldahl, dry basis) such that a 35 percent by weight aqueous solution has a minimum viscosity of 75 centipoises at 25 °C, as determined by Brookfield viscometer using a No. 1 spindle at 12 r.p.m Polyamide-epichlorohydrin water-soluble thermosetting resins [CAS Reg. No. 68583-79-9] prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture such that the finished resins have a nitrogen content of 17.0 to 18.0 percent of a dry basis, and that a 30-percent-byweight aqueous solution has a minimum viscosity of 350 centipoises at 20 °C, as determined by a Brookfield viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method)

Polyamide-epichlorohydrin water-soluble thermosetting resin (CAS Reg. No. 96387-48-3) prepared by reacting *N*-methyl-bis(3-aminopropyl) amine with oxalic acid and urea to form a basic polyamide and further reacting the polyamide with epichlorohydrin

Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid, isophthalic acid, itaconic acid or dimethyl glutarate with

Limitations

limited to use at a level not to exceed 0.09 mg/in² of the finished paper and paperboard. For use only as a drainage aid, retention aid, or dry-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.25 percent by weight of finished dry paper and paperboard fibers, when such paper or paperboard is used in contact with fatty foods under conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and

paperboard and used at a level not to exceed

0.2 percent dry resin by weight of finished dry

paper or paperboard fibers.

For use only under the following conditions:

1. As a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.12 percent by weight of dry paper or paperboard.

2. The finished paper or paperboard will be used in contact with food only of the types identified in paragraph (c) of this section, table 1, under types I and IV-B and under conditions of use described in paragraph (c) of this section, table 2, conditions of use F and G.

For use only as a wet strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.5 percent by weight of dry paper and paperboard fibers.

For use only in the manufacture of paper and paperboard under conditions such that the resins do not exceed 1.5 percent by weight of

List of Substances Limitations diethylenetriamine to form a basic polyamide and the paper or paperboard. further reacting the polyamide with one of the following: Epichlorohydrin. Epichlorohydrin and ammonia mixture. Epichlorohydrin and sodium hydrosulfite mixture. Polyamidoamine-ethyleneimine-epichlorohydrin resin For use only as a retention aid employed prepared by reacting hexanedioic acid, prior to the sheet-forming operation in the manufacture of paper and paperboard at a N-(2-aminoethyl)-1,2-ethanediamine, (chloromethyl)oxirane, ethyleneimine (aziridine), and level not to exceed 0.12 percent resin by polyethylene glycol, partly neutralized with sulfuric acid weight of the finished dry paper or (CAS Reg. No. 167678-45-7) paperboard. Polyamidol-epichlorohydrin modified resin produced by For use only as a wet strength agent reacting glutaric acid dimethyl ester with diethyleneemployed prior to the sheet-forming triamine to produce a basic polyamide which is modified operation in the manufacture of paper and by reaction with formaldehyde and further reacted with paperboard, and used at a level not to exceed epicholorohydrin to form a water soluble cationic resin 2.5 percent by weight of dry paper and having a nitrogen content of 10.9-11.9 percent and a paperboard fibers when such paper or chlorine content of 13.8-14.8 percent, on a dry basis, and paperboard is used in contact with food a minimum viscosity, in 12.5 percent by weight aqueous under conditions of use E through G solution, of 10 centipoises at 25 °C, as determined by a described in table 2 of paragraph (c) of this Brookfield Model LVF viscometer using a No. 1 spindle section. at 60 r.p.m. (or equivalent method) Polyamine-epichlorohydrin resin produced by the For use only as a flocculant, drainage aid, reaction of epichlorohydrin with monomethylamine to formation aid, retention aid, or strength form a prepolymer and further reaction of this additive employed prior to the sheet-forming prepolymer with N,N,N',N'-tetramethylethylenediamine operation in the manufacture of paper and such that the finished resin having a nitrogen content of paperboard, and used at a level not to exceed 11.6 to 14.8 percent and a chlorine content of 20.8 to 0.12 percent by weight of dry paper and 26.4 percent and a minimum viscosity, in 25 percent by paperboard fibers. weight aqueous solution, of 500 centipoises at 25 °C, as determined by LV-series Brookfield viscometer using a No. 2 spindle at 12 r.p.m. (or by other equivalent method) For use only as a clarifier in the treatment of Polyamine-epichlorohydrin resin produced by the reaction of N,N-dimethyl-1,3-propanediamine with influent water to be used in the manufacture epichlorohydrin and further reacted with sulfuric acid, of paper and paperboard, and used at a level Chemical Abstracts Service Registry Number not to exceed 20 parts per million of the [27029-41-0], such that the finished resin has a influent water. maximum nitrogen content of 14.4 percent (dry basis) and a minimum viscosity in 30 percent by weight aqueous solution (pH 4-6) of 50 centipoises at 25 °C, as determined by Brookfield LVT model viscometer, using a No. 1 spindle at 12 r.p.m. (or equivalent method) Polyamine-epichlorohydrin water-soluble thermosetting For use only as a wetstrength agent and/or

resin produced by reacting epichlorohydrin with: (i) polyamines comprising at least 95 percent by weight C_4 to C_6 aliphatic diamines and/or their self-condensation products, and/or (ii) prepolymers produced by reacting 1,2-dichloroethane with the polyamines in (i). The finished resin has a nitrogen content of 5.0 to 9.0 percent, a chlorine content of 18.0 to 35.0 percent on a dry basis, and a minimum viscosity, in a 25 percent by weight aqueous solution, of 50 centipoises at 20 °C (68 °F), as determined by Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method)

Polyamine-epichlorohydrin water-soluble thermosetting resin produced by reacting epichlorohydrin with: (i) polyamines comprising at least 95 percent by weight C₄ to C₆ aliphatic diamines and/or their self-condensation products and/or (ii) hexamethylenediamine, and/or (iii) bis(hexamethylene) triamine and higher homologues, and/or (iv) prepolymers produced by reacting 1,2-dichloroethane with the polyamines in (i) and/or (ii) and/or (iii). The finished resin has a nitrogen content of 5.0 to 9.0 percent, a chlorine content of 18.0 to 35.0 percent on a dry basis, and a minimum viscosity, in a 25 percent by weight aqueous solution, of 50 centipoises at 20 °C (68 °F), as determined by Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method)

Polyamine-epichlorohydrin water soluble thermosetting resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting this prepolymer with epichlorohydrin. This resin is then reacted with nitrilotris (methylene-phosphonic acid), pentasodium salt, such that the finished resin has a nitrogen content of 5.0-5.3 percent; a chlorine content of 29.7-31.3 percent; and a phosphorus content of 2.0-2.2 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 25 °C., as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method)

Polyamine resin produced by the reaction of 1,2-dichloroethane with bis(hexamethylene)triamine and higher homologues such that the finished resin has a nitrogen content of 13.0-15.0 percent on a dry basis, and

Limitations

retention aid employed prior to the sheetforming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.

For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.

For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.

For use only as a retention aid and/or flocculent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not

a minimum viscosity in 25-percent-by-weight aqueous solution of 75 centipoises at 25 °C., as determined by Brookfield HAT model viscometer using a No. 1 spindle at 50 r.p.m. (or equivalent method)

Polyaminoamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylenetriamine to produce a polyamide which is modified by reaction with diethylaminopropylamine and further reacted with dichloroethyl ether to form a polyamide intermediate. This polyamide intermediate is then reacted with epichlorohydrin such that the finished resins have a nitrogen content of 10.9-12.4 percent (Kjeldahl, dry basis) and a minimum viscosity in 40 percent-by-weight aqueous solution of 250 centipoises at 22 °C, as determined by a Brookfield Model LVT viscometer using a No. 2 spindle at 30 r.p.m. (or equivalent method) Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter Poly(diallyldimethylammonium chloride) (CAS Reg. No. 26062-79-3) produced by the polymerization of (diallyldimethylammonium chloride) so that the finished resin has a nitrogen content of 8.66±0.4 percent on a dry weight basis and a minimum viscosity in a 40 percent by weight aqueous solution of 1,000 centipoises at 25 °C (77 °F), determined by LVF Model Brookfield Viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method). The level of residual monomer is not to exceed 1 percent by weight of the polymer (dry basis)

Poly (diallyldimethylammonium chloride) (CAS Reg. No. 26062-79-3) produced by the polymerization of diallyldimethylammonium chloride so that the finished resin has a nitrogen content of 8.66±0.4 percent on a dry basis and a minimum viscosity in a 15 weight-percent aqueous solution of 10 centipoises at 25 °C (77 °F), as determined by LVF Model Brookfield viscometer using a No. 1 spindle at 60 r/min (or equivalent method). The level of residual monomer is not to exceed 1 weight-percent of the polymer (dry basis)

Poly(1,2-dimethyl-5-vinylpyridinium methyl sulfate) having a nitrogen content of 5.7 to 7.3 percent and a sulfur content of 11.7 to 13.3 percent by weight on a dry basis and having a minimum viscosity in 30-percent-byweight aqueous solution of 2,000 centipoises at 25 °C.,

Limitations

to exceed 0.1 percent by weight of dry paper or paperboard fibers.

For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.5 percent by weight of the finished dry paper and paperboard.

For use only as provided in §§ 175.300, 178.3740 and 178.3860 of this chapter.

For use only:

- 1. As a pigment dispersant and/or retention aid prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 10 pounds of active polymer per ton of finished paper and paperboard.
- 2. As a pigment dispersant in coatings at a level not to exceed 3.5 pounds of active polymer per ton of finished paper and paperboard.

For use only as a flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 10 mg/L (10 parts per million) of influent water.

For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.

List of Substances Limitations as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 60 r.p.m Polyester resin produced by reacting For use only as a surface-sizing compound dimethylolpropionic acid (CAS Registry No. 4767-03-7) applied after the sheet-forming operation in as a comonomer, at no more than 30 percent by weight the manufacture of paper and paperboard of total polymer solids in reaction with and limited to use at levels not to exceed 0.1 2,2-dimethyl-1,3-propanediol, phthalic anhydride and percent by weight of finished dry paper or isophthalic acid, such that the polyester resin has a paperboard. viscosity of 200-600 centipoises at 80 °F as determined by a Brookfield RVT viscometer using a number 3 spindle at 50 rpm (or equivalent method) Polyethylene, oxidized; complying with the identity For use only as component of coatings that prescribed in § 177.1620(a) of this chapter contact food only of the type identified under Type VII-B of table 1 in paragraph (c) of this section, and limited to use at a level not to exceed 50 percent by weight of the coating solids. Polyethyleneamine mixture produced when 1 mole of For use only as a retention aid employed prior to the sheet-forming operation in the ethylene dichloride, 1.05 moles of ammonia, and 2 moles of sodium hydroxide are made to react so that a manufacture of paper and paperboard. 10 percent aqueous solution has a minimum viscosity of 40 centipoises at 77 °F, as determined by Brookfield viscometer using a No. 1 spindle at 60 r.p.m Polyethylene glycol (200) dilaurate For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation. Polyethylene glycol (400) dioleate Polyethylene glycol (400) esters of coconut oil fatty acids Polyethylene glycol (600) esters of tall oil fatty acids Polyethylene glycol (400) monolaurate Polyethylene glycol (600) monolaurate Polyethylene glycol (400) monooleate Polyethylene glycol (600) monooleate Polyethylene glycol (400) monostearate Polyethylene glycol (600) monostearate Polyethylene glycol (3,000) monostearate Polyethylenimine, produced by the polymerization of For use only as an adjuvant employed prior ethylenimine to sheet formation in paper-making systems operated at a pH of 4.5 or higher, and limited to use at a level not to exceed 5% by weight of finished dry paper or paperboard fibers.

Poly(isobutene)/maleic anhydride adduct, diethanolamine reaction product. The mole ratio of poly(isobutene)/maleic anydride adduct to diethanolamine is 1:1

Polymethacrylic acid, sodium salt, having a viscosity in 30-percent-by-weight aqueous solution of 125-325 centipoises at 25 °C as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 60 r.p.m

Polymethacrylic acid, sodium salt, having a viscosity in 40-percent-by-weight aqueous solution of 400-700 centipoises at 25 °C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m

Poly[(methylimino)(2-hydroxytrimethylene)hydrochloride] produced by reaction of 1:1 molar ratio of methylamine and epichlorohydrin so that a 31-percent aqueous solution at 25 °C has a Stokes viscosity range of 2.5-4.0 as determined by ASTM method D1545-76 (Reapproved; 1981), "Standard Test Method for Viscosity of Transparent Liquids by Bubble Time Method," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal_register/code_of_federal_regulations/ ibr_locations.html.

(dimethyliminio) ethylene dichloride] produced by reacting equimolar quantities of *N,N,N,N*-tetramethylethylene-diamine and dichlorethyl ether to yield a solution of the solid polymer in distilled water at 25 °C with a reduced viscosity of not less than 0.15 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for -Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National

Poly[oxyethylene (dimethyliminio) ethylene

Limitations

For use only as a surfactant for dispersions of polyacrylamide retention and drainage aids employed prior to the sheet formation operation in the manufacture of paper and paperboard.

For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.3% by weight of coating solids.

For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.1% by weight of coating solids.

For use only as a retention aid employed prior to the sheet-forming operation in such an amount that finished paper and paperboard will contain the additive at a level not in excess of 1 percent by weight of the dry paper and paperboard.

For use only to improve dry-strength of paper and paperboard and as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.1 percent by weight of the finished dry paper and paperboard fibers.

List of Substances	Limitations
Archives and Records Administration (NARA). For	
information on the availability of this material at NARA,	
call 202-741-6030, or go to: http://www.archives.gov/	
federal_register/code_of_federal_regulations/	
ibr_locations.html.). The following formula is used for	
determining reduced viscosity:	
Reduced viscosity in terms of deciliters per gram = $(t - t_0)$ / $(t - C)$,	
where:	
t = Solution efflux time	
t _o = Water efflux time	
C = Concentration of solution in terms of grams per deciliter	
Polypropylene glycol (minimum molecular weight 1,000)	
Potassium persulfate	
2-Propenoic acid, telomer with sodium	For use only as a deposit control additive
2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propane	employed prior to the sheet forming
sulfonate and sodium phosphinate (CAS Reg. No.	operation in the manufacture of paper and
110224-99-2)	paperboard and at a level not to exceed 0.15 percent by weight of the dry paper and
	paperboard.
Propylene glycol alginate	
Protein hydrolysate from animal hides or soybean	
protein condensed with oleic and/or stearic acid	
Rapeseed oil, sulfated ammonium, potassium, or	
sodium salt	
Ricebran oil, sulfated ammonium, potassium, or sodium salt	
Rosin and rosin derivatives	As provided in § 178.3870 of this chapter.
Siloxanes (silicones), dimethyl, isopropyl methyl, methyl	For use only as a component of polyolefin
1-methyl-C ₉₋₄₉ -alkyl (CAS Reg. No. 144635-08-5)	coatings with § 177.1520 of this chapter at a
	level not to exceed 3 percent by weight. The finished coating will be used only for paper
	and paperboard that contact food of types
	VI-A and VI-B of table 1 in paragraph (c) of
	this section, and under conditions of use C,
	D, and E, as described in table 2 in paragraph
	(c) of this section, with a maximum hot fill
	temperature of 200 °F (94 °C).
Silver chloride-coated titanium dioxide	For use only as a preservative in polymer
	latex emulsions at a level not to exceed 2.2
	parts per million (based on silver ion concentration) in the dry coating.
	concentration) in the dry coating.

List of Substances	Limitations
Sodium carboxymethyl guar gum having a minimum viscosity of 2,700 centipoises at 25 °C after 24 hours as determined by RV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 20 r.p.m. and using a test sample prepared by dissolving 8 grams of sodium carboxymethyl guar gum in 392 milliliters of 0.2-percent-by-weight aqueous sodium o-phenylphenate solution Sodium dioctyl sulfosuccinate	For use only as a dry-strength and formation- aid agent employed prior to the sheet- forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of finished dry paper or paperboard fibers.
Sodium formaldehyde sulfoxylate	For use only as polymerization catalyst.
Sodium hypochlorite	
Sodium N-methyl-N-oleyltaurate	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Sodium nitrite	For use only: 1. At levels not to exceed 0.2% by weight of lubricants or release agents applied at levels not to exceed 1 lb. per ton of finished paper or paperboard. 2. As an anticorrosion agent at levels not to exceed 0.2% by weight of wax emulsions used as internal sizing in the manufacture of paper and paperboard prior to the sheetforming operation.
Sodium persulfate	
Sodium polyacrylate	For use only: 1. As a thickening agent for natural rubber latex coatings, provided it is used at a level not to exceed 2 percent by weight of coating solids. 2. As a pigment dispersant in coatings at a level not to exceed 0.25 percent by weight of pigment.
Sodium poly(isopropenylphosphonate) (CAS Reg. No. 118632-18-1)	For use only in paper mill boilers.
Sodium zinc potassium polyphosphate (CAS Reg. No. 65997-17-3)	For use only as a pigment dispersant in coatings at a level not to exceed 1 percent by weight of pigment.
Sperm oil, sulfated, ammonium, potassium, or sodium salt Stannous oleate Stearyl-2-lactylic acid and its calcium salt Styrene-butadiene copolymers produced by	

List of Substances	Limitations
copolymerizing styrene-butadiene with one or more of	
the monomers: acrylamide, acrylic acid, fumaric acid,	
2-hydroxyethyl acrylate, itaconic acid, methacrylic acid,	
and N-methylolacrylamide (CAS Reg. No. 53504-31-7).	
The finished copolymers shall contain not more than 10	
weight percent of total polymer units derived from	
acrylic acid, fumaric acid, 2-hydroxyethyl acrylate,	
itaconic acid, and methacrylic acid, and shall contain not	
more than 3 weight percent of total polymer units	
derived from <i>N</i> -methylolacrylamide, and shall contain not more than 2 weight percent of polymer units derived	
from acrylamide.	
Styrene-maleic anhydride copolymer, amidated,	For use only as a surface size at a level not
ammonium sodium salt; having, in a 25 percent by	to exceed 1 percent by weight of paper or
weight aqueous solution at pH 8.8, a minimum viscosity	paperboard substrate.
of 600 centipoises at 25 °C as determined by Brookfield	par state and st
model LVT viscometer using a No. 3 spindle at 60 r.p.m.	
(or equivalent method)	
Styrene-maleic anhydride copolymer, sodium salt	For use only:
(minimum molecular weight 30,000)	1. As a coating thickening agent at a level not
	to exceed 1% by weight of coating solids.
	2. As surface size at a level not to exceed 1%
	by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymer, potassium salt	For use only as a coating thickening agent at
(minimum molecular weight 30,000)	a level not to exceed 1% by weight of coating
	solids.
Synthetic wax polymer prepared by the catalytic	For use only as a component of petroleum
polymerization of alpha olefins such that the polymer	wax and/or synthetic petroleum wax
has a maximum iodine number of 18 and a minimum	complying with § 178.3710 or § 178.3720 of
number average molecular weight of 2,400	this chapter at levels not to exceed 5 percent by weight of the wax:
	1. Under conditions of use F and G described
	in table 2 of paragraph (c) of this section for
	all foods.
	2. Under conditions of use E described in
	table 2 of paragraph (c) of this section for
	food Types I, II, IV-B, VI, VII-B and VIII as
	described in table 1 of paragraph (c) of this
	section.
Tallow	
Tallow alcohol	
Tallow alcohol, hydrogenated	
Tallow fatty acid, hydrogenated	

List of Substances	Limitations
Tallow hydrogenated	
Tallow sulfated, ammonium, potassium, or sodium salt	
Tetraethylenepentamine	For use only as a modifier for amino resins.
1,4,4a,9a-Tetrahydro-9, 10-anthracenedione (CAS Reg. No. 56136-14-2)	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.
N,N,N', N'-Tetramethylethylenediamine polymer with bis- (2-chloroethyl) ether, first reacted with not more than 5 percent by weight 1-chloro-2,3-epoxypropane and then reacted with not more than 5 percent by weight poly (acrylic acid) such that a 50 percent by weight aqueous solution of the product has a nitrogen content of 4.7-4.9 percent and viscosity of 350-700 centipoises at 25 °C as determined by LV series Brookfield viscometer using a No. 2 spindle at 60 r.p.m. (or by other equivalent method)	For use only as a flocculent, drainage aid or retention aid employed prior to the sheet forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.2 percent by weight of the finished dry paper and paperboard fibers.
Tetrasodium <i>N</i> - (1,2-dicarboxyethyl) - <i>N</i> - octadecylsulfosuccinamate	For use only as an emulsifier in aqueous dispersions of rosin sizes complying with § 178.3870(a)(4) of this chapter and limited to use prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.02 pct by weight of finished paper and paperboard.
Triethanolamine	For use only to adjust pH during the manufacture of amino resins permitted for use as components of paper and paperboard.
Triethylene glycol adipic acid monoester produced by reacting equimolar quantities of triethylene glycol and adipic acid	For use only as a curl-control agent at a level not to exceed 2% by weight of coated or uncoated paper and paperboard.
Triethylenetetramine	For use only as a modifier for amino resins.
1,3,5-Triethylhexahydro-1,3,5-triazine (CAS Registry No. 7779-27-3)	For use only as an antimicrobial agent for coating, binder, pigment, filler, sizing, and similar formulations added prior to the heat drying step in the manufacture of paper and paperboard and limited to use at a level between 0.05 and 0.15 percent by weight of the formulation.
Undecafluorocyclohexanemethanol ester mixture of dihydrogen phosphate, compound with 2,2' iminodiethanol (1:1); hydrogen phosphate, compound with 2,2'-iminodiethanol (1:1); and P,P'-dihydrogen	For use only as an oil repellent at a level not to exceed 0.087 lb (0.046 lb of fluorine) per 1,000 ft ² of treated paper or paperboard, as determined by analysis for total fluorine in

List of Substances	Limitations
pyrophosphate, compound with 2,2'-iminodiethanol (1:2); where the ester mixture has a fluorine content of 48.3 pct to 53.1 pct as determined on a solids basis	the treated paper or paperboard without correction for any fluorine which might be present in the untreated paper or paperboard, when such paper or paperboard is used in contact with food only of the types identified in paragraph (c) of this section, table 1, under Types IVA, V, VIIA, VIII, and IX, and under the conditions of use B through G described in table 2 of paragraph (c) of this section.
Viscose rayon fibers	
Wax, petroleum Xanthan gum, conforming to the identity and specifications prescribed in § 172.695 of this chapter, except that the residual isopropyl alcohol shall not exceed 6,000 parts per million	Complying with § 178.3710 of this chapter. For use only at a maximum level of 0.125 percent by weight of finished paper as a suspension aid or stabilizer for aqueous pigment slurries employed in the manufacture of paper and paperboard.
Xylene sulfonic acid-formaldehyde condensate, sodium salt	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Zeolite Na-A (CAS Reg. No. 68989-22-0)	For use as a pigment extender at levels not to exceed 5.4 percent by weight of the finished paper and paperboard.
Zinc formaldehyde sulfoxylate Zinc octoate	For use only as polymerization catalyst.
Zirconium oxide	For use only as a component of waterproof coatings where the zirconium oxide is present at a level not to exceed 1 percent by weight of the dry paper or paperboard fiber and where the zirconium oxide is produced by hydrolysis of zirconium acetate.

- (b) Substances identified in paragraphs (b)(1) and (2) of this section may be used as components of the food-contact surface of paper and paperboard, provided that the food-contact surface of the paper or paperboard complies with the extractives limitations prescribed in paragraph (c) of this section.
 - (1) Substances identified in § 175.300(b)(3) of this chapter with the exception of those identified in paragraphs (b)(3)(v), (xv), (xx), (xxvi), (xxxi), and (xxxii) of that section and paragraph (a) of this section.

(2) Substances identified in this paragraph (b)(2) follow:

List of substances	Limitations
Acrylamide copolymerized with ethyl acrylate and/or stryene and/or methacrylic acid, subsequently reacted with formaldehyde and butyl alcohol	
Acrylamide copolymerized with ethylene and vinyl chloride in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide, and in such a manner that the acrylamide portion may or may not be subsequently partially hydrolyzed	For use only as coatings or components of coatings.
2-Acrylamido-2-methyl-propanesulfonic acid, homopolymer, sodium salt (CAS Reg. No. 35641-59-9)	For use only in coatings at a level not to exceed 0.01 mg/in ²
Acrylic and modified acrylic polymers	Complying with § 177.1010 of this chapter.
Acrylic copolymers produced by copolymerizing 2 or more of the acrylate monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and <i>n</i> -propyl methacrylate, or produced by copolymerizing one or more of such acrylate monomers together with one or more of the monomers acrylic acid, acrylonitrile, butadiene, 2-ethyl-hexyl acrylate, fumaric acid, glycidyl methacrylate, <i>n</i> -hexyl-methacrylate, itaconic acid, methacrylic acid, styrene, vinyl acetate, vinyl chloride, and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from one or more of the monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and <i>n</i> -propyl methacrylate; and shall contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, glycidyl methacrylate, <i>n</i> -hexyl methacrylate, itaconic acid, and methacrylic acid. The provision limiting the finished acrylic copolymers to not more than 5 units derived from acrylic acid, fumaric acid, glycidyl methacrylate, <i>n</i> -hexyl methacrylate, itaconic acid, and methacrylic acid is not applicable to finished acrylic copolymers used as coating adjuvants at a level not exceeding 2 weight percent of total coating solids	
Alkyl mono- and disulfonic acids, sodium salts (produced from $\textit{n}\text{-alkanes}$ in the range of $C_{10}\text{-}C_{18}$ with not less than 50 percent $C_{14}\text{-}C_{16}$).	For use only: 1. As emulsifiers for vinylidene chloride copolymer coatings and limited to use at levels not to exceed 2 percent by weight of the coating solids.

List of substances	Limitations
2-Bromo-4'-hydroxyacetophenone	2. As emulsifiers for vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of types identified in paragraph (c) of this section, table 1, under Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX and under conditions of use E, F, and G described in table 2 of paragraph (c) of this section. For use only as a preservative for coating formulations, binders, pigment slurries, and sizing solutions at a level not to
Butanedioic acid, sulfo-1,4-di-(C_9 - C_{11} alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	exceed 0.006 percent by weight of the coating, solution, slurry or emulsion. For use as a surface active agent in package coating inks at levels not to exceed 3 percent

List of substances	Limitations
	by weight of the coating ink.
Butyl oleate, sulfated, ammonium, potassium, or sodium salt Butyraldehyde	
Captan (<i>N</i> -trichloromethylmercapto-4-cyclohexene-1, 2-dicarboximide)	For use only as a mold- and mildew-proofing agent in coatings intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under Type I, II, VI-B, and VIII.
Castor Oil, polyoxyethylated (42 moles ethylene oxide)	For use only as an emulsifier in nitrocellulose coatings for paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under Types IV A, V, VII A, VIII, and IX; and limited to use at a level not to exceed 8 percent by weight of the coating solids.
1-(3-Chloroallyl)-3,5,7-triaza-1- azoniaadamantane chloride (CAS Reg. No. 4080-31-3)	For use only: 1. As a preservative at a level of 0.3 weight percent in latexes used as pigment binders in paper and paperboard

intended for use in contact with nonacidic, nonalcoholic food and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. As a preservative at a level not to exceed 0.07 weight percent in latexes and 0.05 weight percent in latexes and 0.05 weight percent in pigment slurries used as components of coatings for paper and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 262-20-4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight) 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paper and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and paperboard int	intended for use in contact with nonacidic, nonalcoholic food	List of substances	Limitations
coating	conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. As a preservative at a level not to exceed 0.07 weight percent in latexes and 0.05 weight percent in pigment slurries used as components of coatings for paper and paperboard intended for use in contact with food. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight) 1 As an antimicrobial agent for polymer latex emulsions in paper coatings at a level not to exceed 50 parts per million (based on isothiazolone active ingredients) in the coating formulatiton. 2. As an antimicrobial agent for finished	2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2). The mixture may contain magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active	intended for use in contact with nonacidic, nonalcoholic food and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. As a preservative at a level not to exceed 0.07 weight percent in latexes and 0.05 weight percent in pigment slurries used as components of coatings for paper and paperboard intended for use in contact with food. For use only: 1. As an antimicrobial agent for polymer latex emulsions in paper coatings at a level not to exceed 50 parts per million (based on isothiazolone active ingredients) in the coating formulation. 2. As an antimicrobial agent for finished

List of substances	Limitations
	levels not more
	than 0.05 weight
	percent and not
	less than 0.01
	weight percent: in
	latexes used as
	pigment binders
	in coatings; in
	pigment slurries
	used in coatings;
	and/or in
	coatings
	themselves. The
	total level of the
	preservative in
	the finished
	coating shall not
	exceed 0.04
	weight percent of
	the finished
	coating solids.
Dibutyl sebacate	
Di(C ₇ ,C ₉ -alkyl) adipate	Complying with §
	178.3740 of this
	chapter.
Dicyclohexyl phthalate	
Diethylene glycol dibenzoate (CAS Reg. No. 120-55-8)	For use only as a
	plasticizer for
	polyvinyl acetate
	coatings at a level
	not to exceed 5
	percent by weight
	of the coating
	solids under
	conditions
	described in
	paragraph (c) of
	this section, table
	2, conditions of
	use E, F, and G.
Diethylene glycol ester of the adduct of terpene and maleic anhydride	
Dihydroxy dichlorodiphenyl methane	For use only as
	preservative for
	coating
	1 3

List of substances	Limitations
	formulations.
Dimethylpolysiloxane, 100 centistokes viscosity	
Dimethylpolysiloxane-beta-phenylethyl methyl polysiloxane copolymer (2:1), 200 to 400 centistokes viscosity	
<i>N,N'</i> -Diphenyl- <i>p</i> -phenylenediamine	For use only as polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
Dipropylene glycol dibenzoate (CAS Reg. No. 27138-31-4)	1. For use only as a plasticizer for polyvinyl acetate coatings at a level not to exceed 5 percent by weight of the coating solids under conditions described in paragraph (c) of this section, table 2, condition of use E. 2. For use only as a plasticizer for polyvinyl acetate coatings at a level not to exceed 10 percent by weight of the coating solids under conditions described in paragraph (c) of this section, table 2, conditions of
Disodium N-octadecylsulfosuccinamate	use F and G. For use only as an emulsifier in resin latex coatings and limited to use at a level not to exceed 0.05% by

List of substances	Limitations
	weight of the coating solids.
EDTA (ethylenediaminetetraacetic acid) and its sodium and/or calcium salts	
Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-2(1H)pyrimidinone, propoxylated (CAS Reg. No. 118299-90-4)	For use only as an insolubilizer for starch-based coatings and limited to use at a level not to exceed 5.0 percent by weight of the coating.
Ethylene-acrylic acid copolymers produced by the copolymerization of ethylene and acrylic acid and/or their partial ammonium salts. The finished copolymer shall contain no more than 25 weight percent of polymer units derived from acrylic acid and no more than 0.35 weight percent of residual monomeric acrylic acid, and have a melt index not to exceed 350 as determined by ASTM method D1238-82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	
Formaldehyde	For use only as preservative for coating formulations.
Glyoxal	For use only as an insolubilizing agent in starchand protein-based coatings that contact nonalcoholic foods, and limited to use at a level not to exceed 6 percent by weight of the starch or protein fraction of the coating solids.

List of substances	Limitations
Glyceryl monobutyl ricinoleate	
Hydroxymethyl derivatives (mixture of mono and poly) of [N-(1, 1-dimethyl-3-oxobutyl) acrylamide] produced by reacting 1 mole of the [N-(1,1-dimethyl-3-oxobutyl) acrylamide] with 3 moles of formaldehyde such that the finished product has a maximum nitrogen content of 6.2 percent and a maximum hydroxyl content of 15 percent by weight on a dry basis	For use only as a comonomer in polyvinyl acetate latex coatings and limited to use at a level not to exceed 1 percent by weight of dry polymer solids.
Isobutyl oleate, sulfated, ammonium, potassium, or sodium salt	
Maleic anhydride adduct of butadiene-styrene copolymer α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1α-methylstyrene to	
3 vinyltoluene)	
Modified kaolin clay (CAS Reg. No. 1344-00-9) is produced by the reaction of sodium silicate (CAS Reg. No. 1344-09-8) and kaolinite clay (CAS Reg. No. 1332-58-7) under hydrothermal conditions. The reaction product has a molecular weight between 246 and 365 and consists of 46 to 55 percent silicon dioxide (Si0 ₂), 28 to 42 percent aluminum oxide (A1 ₂ 0 ₃), and 2 to 7 percent of sodium oxide (Na ₂ 0). The reaction product will not consist of more than 70 percent modified kaolin clay	For use only as a component of coatings in paper and paperboard products at a level not to exceed 9 percent by weight of the coating intended for use in contact with food of Types I through IX described in table 1 of paragraph (c) of this section under conditions of use C through H described in table 2 of paragraph (c) of this section.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt	
Oleyl alcohol Oxazolidinylethylmethacrylate (CAS Registry No. 46236-15-1) copolymer with ethyl acrylate and methyl methacrylate, and containing not more than 6 percent by weight of oxazolidinylethylmethacrylate. Maximum nitrogen content shall be 0.5 percent and number average molecular weight of that portion of the copolymer soluble in tetrahydrofuran shall be not less than 50,000	For use only as a binder for pigment coatings as a binder level not to exceed 4.0 percent by weight of dry paper or

List of substances	Limitations
	paperboard.
Pentaerythritol tetrastearate	
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof,	For use only as
meeting the following specifications: Softening point 97 °C minimum, as	modifiers in
determined by ASTM method E28-67 (Reapproved 1982), "Standard Test	waxpolymer blend
Method for Softening Point by Ring and Ball Apparatus;" aniline point 120 °C	coatings for
minimum, as determined by ASTM method D611-82, "Standard Test Methods	corrugated
for Aniline Point and Mixed Aniline Point of Petroleum Products and	paperboard
Hydrocarbon Solvents," which are incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr.,	intended for use in bulk packaging
West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the	or raw fruits, raw
National Archives and Records Administration (NARA). For information on the	vegetables, iced
availability of this material at NARA, call 202-741-6030, or go to:	meat, iced fish,
http://www.archives.gov/federal_register/code_of_federal_regulations/	and iced poultry;
ibr_locations.html.). Specific gravity 0.96-0.99 (20 °C/20 °C). Such petroleum	and limited to use
hydrocarbon resins are produced by the catalytic polymerization of dienes and	at a level not to
olefins from low-boiling distillates of cracked petroleum stocks that contain no	exceed 30 weight-
material boiling over 200 °C and that meet the ultraviolet absorbance limits	percent of the
prescribed in § 172.880(b) of this chapter when subjected to the analytical	coating solids.
procedure described in § 172.886(b) of this chapter, modified as follows: Treat	
the product as in the first paragraph under "Procedure" in § 172.250(b)(3) of this chapter. Then proceed with § 172.886(b) of this chapter, starting with the	
paragraph commencing with "Promptly complete transfer of the sample * * *"	
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic	
anhydride, maleic anhydride and ethylene glycol, such that the polyester resin	
has an acid number of 4 to 11, a drop-softening point of 70 °C-92 °C., and a	
color of K or paler	
Polyester resin produced by reacting the acid groups in montan wax with	
ethylene glycol	
Polyethylene, oxidized	Complying with §
	177.1620 of this
	chapter.
Polyethylene reacted with maleic anhydride such that the modified	
polyethylene has a saponification number not in excess of 6 after Soxhlet	
extraction for 24 hours with anhydrous ethyl alcohol	Natta avasad
Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt	Not to exceed 300 p.p.m. in
	finished coated
	paper or
	paperboard.
Polyoxypropylene-polyoxyethylene block polymers (minimum molecular weight	
6,800)	
Polyvinyl acetate	
	Į.

List of substances	Limitations
Polyvinyl alcohol (minimum viscosity of 4% aqueous solution at 20 °C. of 4 centipoises) Polyvinyl butyral Polyvinyl formal Polyvinyl pyrrolidone Polyvinyl stearate Propylene glycol mono- and diesters of fats and fatty acids Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethyl polysiloxane (CAS Reg. Nos. 68083-19-2) and 68083-18-1) with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2) or dimethyl (methyl hydrogen) polysiloxane (CAS Reg. No. 68037-59-2). Diallyl maleate (CAS Reg. No. 999-21-3), dimethyl maleate (CAS Reg. No. 624-48-6), 1-ethynyl-1-cyclohexanol (CAS Reg. No. 78-27-3) and vinyl acetate (CAS Reg. No. 108-05-4) may be used as optional polymerization inhibitors	For use only as a surface coating. Platinum content not to exceed 200 parts per million. 1. In coatings for paper and paperboard provided the coating contacts food only of the types identified in paragraph (c) of this section, table 1, under Types I, II, VI, and VII-B when used under conditions of use E, F, and G described in table 2 of paragraph (c) of this section. 2. In coatings for paper and paperboard provided the coating contacts food only of the types identified in paragraph (c) of this section, table 1, under Types III, IV, V, VII-A, VIII, and IX when used under conditions of use A through
	conditions of use E, F, and G described in table 2 of paragraph (c) of this section. 2. In coatings for paper and paperboard provided the coating contacts food only of the types identified in
	paragraph (c) of this section, table 1, under Types III, IV, V, VII-A, VIII, and IX when used

List of substances	Limitations
	H described in
	table 2 of
	paragraph (c) of
	this section.
Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl	Platinum content not to exceed 100
hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg.	parts per million.
No. 624-48-6), vinyl acetate (CAS Reg. No. 108-05-4), dibutyl maleate (CAS Reg.	For use only as a
No. 105-76-0) and diallyl maleate (CAS Reg. No. 999-21-3) may be used as	release coating
optional polymerization inhibitors. The polymer may also contain C ₁₆ -C ₁₈	for pressure sensitive
olefins (CAS Reg. No. 68855-60-7) as a control release agent	adhesives.
Sodium decylbenzenesulfonate	adirectives.
Sodium dihexyl sulfosuccinate	
Sodium <i>n</i> -dodecylpolyethoxy (50 moles) sulfate-sodium	For use only as an
isododecylphenoxypolyethoxy (40 moles) sulfate mixtures	emulsifier in
	coatings that contact food only
	of the types
	identified in
	paragraph (c) of
	this section, table 1, under Types IV-
	A, V, VII, VIII, and
	IX; and limited to
	use at levels not
	to exceed 0.75 percent by weight
	of the coating
	solids.
Sodium 2-ethylhexyl sulfate	
Sodium oleoyl isopropanolamide sulfosuccinate	
Sodium pentachlorophenate	For use only as
	preservative for coating
	formulations.
Sodium o-phenylphenate	Do.
Sodium vinyl sulfonate polymerized	
Sodium xylenesulfonate (CAS Reg. No. 1300-72-7)	For use only in
	paper and paperboard
	coatings at levels
	not to exceed

List of substances	Limitations
Styrene copolymers produced by copolymerizing styrene with maleic anhydride and its methyl and butyl (sec - or iso -) esters. Such copolymers may contain β -nitrostyrene as a polymerization chain terminator	0.01 percent by weight of the finished paper and paperboard. For use only as a coating or component of coatings and limited to use at a level not to exceed 1% by weight of paper or paperboard substrate.
Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (Mn) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent	For use only in contact with foods of Types IV-A, V, and VII in table 1 of paragraph (c) of this section, under use conditions E through G in table 2 of paragraph (c), and with foods of Types VIII and IX without use temperature restriction.
Styrene-acrylic copolymers (CAS Reg. No. 25950-40-7 produced by polymerizing 77 to 83 parts by weight of styrene with 13 to 17 parts of methyl methacrylate, 3 to 4 parts of butyl methacrylate, 0.5 to 2.5 parts of methacrylic acid, and 0.1 to 0.3 part of butyl acrylate such that the finished copolymers have a minimum number average molecular weight greater than 100,000 and a level of residual styrene monomer in the polymer not to exceed 0.1 percent by weight	For use only as a component of coatings and limited to use at a level not to exceed 20 percent by weight of the coating solids.
Styrene-butadiene copolymers produced by copolymerizing styrene-butadiene with one or more of the monomer: acrylamide, acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and methacrylic acid. The finished copolymers shall contain not more than 10 weight percent of total polymer units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic	

	1
List of substances	Limitations
acid and methacrylic acid, and shall contain not more than 2 weight percent of polymer units derived from acrylamide	
Styrene-butadiene copolymers with 2-hydroxyethyl acrylate and acrylic acid	
containing not more than 15 weight percent acrylic acid and no more than 20	
weight percent of a combination of 2-hydroxyethyl acrylate and acrylic acid	
Styrene-butadiene-vinylidene chloride copolymers containing not more than 40	For use only as
weight percent of vinylidene chloride in the finished copolymers. The finished	coatings or
copolymers may contain not more than 10 weight percent of total polymer	components of
units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and/or methacrylic acid	coatings.
Styrene-dimethylstyrene-a-methylstyrene copolymers produced by	For use only in
polymerizing equimolar ratios of the three comonomers such that the finished	coatings for
copolymers have a minimum average molecular weight of 835 as determined	paper and
by ASTM method D2503-82, "Standard Test Method for Molecular Weight	paperboard
(Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of	intended for use in contact with
Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West	nonfatty food and
Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the	limited to use at a
National Archives and Records Administration (NARA). For information on the	level not to
availability of this material at NARA, call 202-741-6030, or go to:	exceed 50% by
http://www.archives.gov/federal_register/code_of_federal_regulations/	weight of the
ibr_locations.html.	coating solids.
Styrene-isobutylene copolymers (weight average molecular weight not less	For use only in
than 6,300)	coatings for
	paper and
	paperboard intended for use
	in contact under
	conditions of use
	D G described in
	table 2 of
	paragraph (c) of
	this section, with
	food of Types I, II,
	IV-B, VI-B, VII-B,
	and VIII described in table 1 of
	paragraph (c) of
	this section; and
	limited to use at a
	level not to
	exceed 40
	percent by weight
	of the coating

List of substances	Limitations
	solids.
Styrene-maleic anhydride copolymers	For use only as a coating or component of coatings and limited for use at a level not to exceed 2 percent by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymers containing no more than 5 weight percent of polymer units derived from methacrylic acid	
Styrene-vinylidene chloride copolymers containing not more than 40 weight percent of vinylidene chloride in the finished copolymers. The finished copolymers may contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, itaconic acid, and/or methacrylic acid 2-Sulfoethyl methacrylate, sodium salt [Chemical Abstracts Service No. 1804-87-1]	For use only as coatings or components of coatings. For use only in copolymer coatings under conditions of use E, F, and G described in paragraph (c) of this section, table 2, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer
α[p-(1,1,3,3-Tetramethylbutyl) phenyl]-omega-hydroxypoly (oxyethylene) hydrogen sulfate, sodium salt mixture with α-[p-(1,1,3,3-tetramethylbutyl)-phenyl]-omega-hydroxypoly (oxyethylene) with both substances having a poly(oxyethylene) content averaging 3 moles	coating. For use only as a surface-active agent at levels not to exceed 3 percent by weight of vinyl acetate polymer with ethylene and N-(hydroxymethyl) acrylamide intended for use

List of substances	Limitations
List of substances	Limitations in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, table 1, under Types I, II, III, IV, VI-B, and VII, and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, table 1, under Types V, VIII and IX and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use described in paragraph (c) of this section, table 2, conditions of use C, D, E, F, and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use C, D, E, F, and Use III and IX and Use C, D, E, F, and Use III and IX a
Tetrasodium <i>N</i> -(1,2-dicarboxyethyl)- <i>N</i> -octadecylsulfo-succinamate	G. For use only as an emulsifier in resin latex coatings, and limited to use at a level not to exceed 0.05% by weight of the coating solids.
Toluenesulfonamide-formaldehyde resins	
Vinyl acetate copolymers produced by copolymerizing vinyl acetate with one or more of the monomers acrylamide, acrylic acid, acrylonitrile, bicyclo-	

List of substances	Limitations
[2.2.1]hept-2-ene-6-methylacrylate, butyl acrylate, crotonic acid, decyl acrylate, diallyl fumarate, diallyl maleate, diallyl phthalate, dibutyl fumarate, dibutyl itaconate, dibutylmaleate, di(2-ethylhexyl) maleate, divinyl benzene, ethyl acrylate, 2-ethyl-hexyl acrylate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, methyl acrylate, methyl methacrylate, mono(2-ethylhexyl) maleate, monoethyl maleate, styrene, vinyl butyrate, vinyl crotonate, vinyl hexoate, vinylidene chloride, vinyl pelargonate, vinyl propionate, vinyl pyrrolidone, vinyl stearate, and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, crotonic acid, decyl acrylate, dibutyl itaconate, di(2-ethylhexyl) maleate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, mono(2-ethylhexyl) maleate, monoethyl maleate, vinyl butyrate, vinyl hexoate, vinyl pelargonate, vinyl propionate, vinyl stearate, and vinyl sulfonic acid	
Vinyl acetate polymer with ethylene and N-(hydroxymethyl) acrylamide containing not more than 6 weight percent of total polymer units derived from N-(hydroxymethyl) acrylamide	For use only in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, table 1, under Types I, II, III, IV, VI B, and VII and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, table 1, under Types V, VIII, and IX and under the conditions of use described in paragraph (c) of

List of substances	Limitations
	this section, table 2, conditions of use C, D, E, F, and G.
Vinyl chloride copolymers produced by copolymerizing vinyl chloride with one or more of the monomers acrylonitrile; fumaric acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic anhydride; 5-norbornene-2, 3-dicarboxylic acid, mono-n-butyl ester; vinyl acetate-and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl chloride: shall contain no more than 5 weight percent of total polymer units derived from fumaric and/or maleic acid and/or their methyl, ethyl, propyl, butyl, amyl, heptyl, or octyl monoesters or from maleic anhydride or from mono-n-butyl ester of 5-norbornene-2, 3-dicarboxylic acid (however, in any case the finished copolymers shall contain no more than 4 weight percent of total polymer units derived from mono-n-butyl ester of 5-norbornene-2,3-dicarboxylic acid) Vinyl chloride-vinyl acetate hydroxyl-modified copolymers Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimellitic anhydride Vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylamide acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate ethyl acrylate, ethyl methacrylate, fumaric acid, itaconic acid, methacrylate, propyl methacrylate, vinyl chloride and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinylidene chloride; and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid	
Aluminum	For use as a
Aluminum hydroto	colorant only.
Aluminum hydrate Aluminum and potassium silicate (mica)	Do.
Aluminum mono-, di-, and tristearate	Do.
Aluminum silicate (China clay)	Do.
Barium sulfate	Do.
Bentonite	Do.
Bentonite, modified with dimethyldioctadecylammonium ion	Do.
Burnt umber	Do.
Calcium carbonate	Do.

List of substances	Limitations		
Calcium silicate	Do.		
Calcium sulfate	Do.		
Carbon black (channel process)	Do.		
Cobalt aluminate	Do.		
Diatomaceous earth	Do.		
Iron oxides	Do.		
Magnesium oxide	Do.		
Magnesium silicate (talc)	Do.		
Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8)	Do.		
Raw sienna	Do.		
Silica	Do.		
Tartrazine lake (certified FD&C Yellow No. 5 only)	Do.		
Titanium dioxide	Do.		
Titanium dioxide-barium sulfate	Do.		
Titanium dioxide-magnesium	Do.		
silicate			
Zinc carbonate	Do.		
Zinc oxide	Do.		

(c) The food-contact surface of the paper and paperboard in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of this paragraph, shall yield net chloroform-soluble extractives (corrected for wax, petrolatum, mineral oil and zinc extractives as zinc oleate) not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in paragraph (d) of this section.

Table 1—Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
- A. Water-in-oil emulsions, high- or low-fat.

- B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
- A. Moist bakery products with surface containing free fat or oil.
- B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

TABLE 2—TEST PROCEDURES WITH TIME TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM THE FOOD-CONTACT SURFACE OF UNCOATED OR COATED PAPER AND PAPERBOARD, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

	Types	pes Food-s		simulating solvents	
Condition of use	of food	Water	Heptane ¹	8 percent alcohol	50 percent alcohol
	(see table 1)	Time and temperature	Time and temperature	Time and temperature	Time and temperature
A. High temperature heat- sterilized (e.g., over 212 °F)	I, IV-B, VII-B	250 °F, 2 hr			
	III, IV- A, VII- A	do	150 °F, 2 hr		

¹ Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

	Types	es Food-simulating solvents			
Condition of use	of food	Water	Heptane ¹	8 percent alcohol	50 percent alcohol
	(see table 1)	Time and temperature	Time and temperature	Time and temperature	Time and temperature
B. Boiling water sterilized	II, VII-B	212 °F, 30 min			
	III, VII- A	do	120 °F, 30		
C. Hot filled or pasteurized above 150 °F	II, IV-B, VII-B	Fill boiling, cool to 100 °F			
	III, IV- A, VII- A	do	120 °F, 15 min		
D. Hot filled or pasteurized below 150 °F	V, IX II, IV-B, VI-B,		do		
	VII-B III, IV-	150 °F, 2 hr	100 °F, 30		
	A, VII-		min		
	V, IX		do		
	VI-A VI-C			150 °F, 2 hr	150 °F, 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container)	I, II, IV- B, VI-B, VII-B	120 °F, 24 hr			
	III, IV- A, VII- A	do	70 °F, 30 min		
	V, IX VI-A VI-C		do	120 °F, 24 hr	120 °F, 24
F. Refrigerated storage (no thermal treatment in the container)	III, IV- A, VII- A	70 °F, 48 hr	70 °F, 30 min		hr.

¹ Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

	Types	Types Food-simulating solvents			
Condition of use	of food	Water	Heptane ¹	8 percent alcohol	50 percent alcohol
	(see table 1)	Time and temperature	Time and temperature	Time and temperature	Time and temperature
	I, II, IV- B, VI-B, VII-B	do			
	VI-A			70 °F, 48 hr	
	VI-C				70 °F, 48 hr.
G. Frozen storage (no thermal treatment in the container)	I, II, IV- B, VII-B	70 °F, 24 hr			
	III, VII- A	do	70 °F, 30 min		
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:					
Aqueous or oil-in-water emulsion of high- or low-fat	I, II, IV- B, VII-B	212 °F, 30 min			
2. Aqueous, high- or low-free oil or fat	III, IV- A, VII- A, IX	do	120 °F, 30 min		

¹ Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

(d) Analytical methods -

(1) Selection of extractability conditions. First ascertain the type of food product (table 1, paragraph (c) of this section) that is being packed commercially in the paper or paperboard and the normal conditions of thermal treatment used in packaging the type of food involved. Using table 2, paragraph (c) of this section, select the food-simulating solvent or solvents and the time-temperature exaggerations of the paper or paperboard use conditions. Having selected the appropriate food-simulating solvent or solvents and the time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) Reagents —

- (i) Water. All water used in extraction procedures should be freshly demineralized (deionized) distilled water.
- (ii) n-Heptane. Reagent grade, freshly redistilled before use, using only material boiling at 208 °F.

- (iii) Alcohol. 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized) distilled water.
- (iv) *Chloroform*. Reagent grade, freshly redistilled before use, or a grade having an established consistently low blank.
- (3) Selection of test method. Paper or paperboard ready for use in packaging shall be tested by use of the extraction cell described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 21.010-21.015, under "Exposing Flexible Barrier Materials for Extraction," which is incorporated by reference (Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/ code_of_federal_regulations/ibr_locations.html.); also described in ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal_register/code_of_federal_regulations/ibr_locations.html.), except that formed paper and paperboard products may be tested in the container by adapting the in-container methods described in § 175.300(e) of this chapter. Formed paper and paperboard products such as containers and lids, that cannot be tested satisfactorily by any of the above methods may be tested in specially designed extraction equipment, usually consisting of clamping devices that fit the closure or container so that the food-contact surface can be tested, or, if flat samples can be cut from the formed paper or paperboard products without destroying the integrity of the food-contact surface, they may be tested by adapting the following "sandwich" method:

(i) Apparatus.

- (a) Thermostated (±1.0 °F) water bath, variable between 70 °F and 120 °F water bath cover capable of holding at least one 800-milliliter beaker partially submersed in bath.
- (b) Analytical balance sensitive to 0.1 milligram with an approximate capacity of 100 grams.
- (c) Tongs.
- (d) Hood and hot-plate facilities.
- (e) Forced draft oven.

For each extraction, the following additional apparatus is necessary:

- (f) One No. 2 paper clip.
- (g) One 800-milliliter beaker with watch-glass cover.
- (h) One 250-milliliter beaker.
- (i) Five $2^{1}/_{2}$ -inch-square aluminum screens (standard aluminum window screening is acceptable).
- (j) One wire capable of supporting sample stack.
- (ii) Procedure.

- (a) For each extraction, accurately cut eight $2^{1}/_{2}$ -inch-square samples from the formed paper or paperboard product to be tested.
- (b) Carefully stack the eight 2¹/₂-inch-square samples and the five 2¹/₂-inch-square aluminum screens in sandwich form such that the food-contact side of each sample is always next to an aluminum screen, as follows: Screen, sample, sample, screen, sample, screen, etc. Clip the sandwich together carefully with a No. 2 paper clip, leaving just enough space at the top to slip a wire through.
- (c) Place an 800-milliliter beaker containing 100-milliliters of the appropriate food-simulating solvent into the constant temperature bath, cover with a watch glass and condition at the desired temperature.
- (d) After conditioning, carefully lower the sample sandwich with tongs into the beaker.
- (e) At the end of the extraction period, using the tongs, carefully lift out the sample sandwich and hang it over the beaker with the wire.
- (f) After draining, pour the food-simulating solvent solution into a tared 250-milliliter beaker. Rinse the 800-milliliter beaker three times, using a total of not more than 50 milliliters of the required solvent.
- (g) Determine total nonvolatile extractives in accordance with paragraph (d)(5) of this section.
- (4) Selection of samples. Quadruplicate samples should be tested, using for each replicate sample the number of cups, containers, or preformed or converted products nearest to an area of 100 square inches.
- (5) Determination of amount of extractives
 - (i) Total residues. At the end of the exposure period, remove the test container or test cell from the oven and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask or beaker, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking, low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of approximately 221 °F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram, (e). Calculate the extractives in milligrams per square inch of the container or sheeted paper or paperboard surface.
 - (a) Water and 8- and 50-percent alcohol. Milligrams extractives per square inch = (e)/(s).
 - (b) Heptane. Milligrams extractives per square inch=(e)/(s)(F)

where:

- e = Milligrams extractives per sample tested.
- s = Surface area tested, in square inches.

F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.

e' = Chloroform-soluble extractives residue.

ee' = Corrected chloroform-soluble extractives residue.

e' or ee' is substituted for e in the above equations when necessary.

If when calculated by the equations in paragraph (d)(5)(i)(a) and (b) of this section, the extractives in milligrams per square inch exceeds the limitations prescribed in paragraph (c) of this section, proceed to paragraph (d)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residues).

- (ii) Chloroform-soluble extractives residue. Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (e), in the evaporating dish obtained in paragraph (d)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean, tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at approximately 221 °F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue ('). This ' is substituted for e in the equations in paragraph (d)(5)(i)(a) and (b) of this section. If the chloroform-soluble extractives in milligrams per square inch still exceeds the limitation prescribed in paragraph (c) of this section, proceed to paragraph (d)(5)(iii) of this section (method for determining corrected chloroform-soluble extractives residue).
- (iii) Corrected chloroform-soluble extractives residue
 - (a) Correction for zinc extractives. Ash the residue in the evaporating dish by heating gently over a Meker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the evaporating dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (') to obtain the zinc-corrected chloroform-soluble extractives residue (e'). This e' is substituted for e in the equations in paragraph (d)(5)(i)(a) and (b) of this section.
 - (b) Correction for wax, petrolatum, and mineral oil
 - (1) Apparatus. Standard 10 millimeter inside diameter × 60 centimeter chromatographic column (or standard 50-milliliter buret with an inside diameter of 10-11 millimeters) with a stopcock of glass, perfluorocarbon resin, or equivalent material. The column (or buret) may be optionally equipped with an integral coarse, fritted glass disc and the top of the column (or buret) may be optionally fitted with a 100-millimeter solvent reservoir.

- (2) Preparation of column. Place a snug pledget of fine glass wool in the bottom of the column (or buret) if the column (or buret) is not equipped with integral coarse, fritted glass disc. Overlay the glass wool pledget (or fritted glass disc) with a 15-20 millimeter deep layer of fine sand. Measure in a graduated cylinder 15 milliliters of chromatographic grade aluminum oxide (80-200 mesh) that has been tightly settled by tapping the cylinder. Transfer the aluminum oxide to the chromatographic tube, tapping the tube during and after the transfer so as to tightly settle the aluminum oxide. Overlay the layer of aluminum oxide with a 1.0-1.5 centimeter deep layer of anhydrous sodium sulfate and on top of this place an 8-10 millimeter thick plug of fine glass wool. Next carefully add about 25 milliliters of heptane to the column with stopcock open, and allow the heptane to pass through the column until the top level of the liquid just passes into the top glass wool plug in the column, and close stopcock.
- (3) Chromatographing of sample extract
 - (i) For chloroform residues weighing 0.5 gram or less. To the dried and weighed chloroform-soluble extract residue in the evaporating dish, obtained in paragraph (d)(5)(ii) of this section, add 20 milliliters of heptane and stir. If necessary, heat carefully to dissolve the residue. Additional heptane not to exceed a total volume of 50 milliliters may be used if necessary to complete dissolving. Cool to room temperature. (If solution becomes cloudy, use the procedure in paragraph (d)(5)(iii)(b)(3)(ii) of this section to obtain an aliquot of heptane solution calculated to contain 0.1-0.5 gram of chloroform-soluble extract residue.) Transfer the clear liquid solution to the column (or buret). Rinse the dish with 10 millimeters of additional heptane and add to column. Allow the liquid to pass through the column into a clean, tared evaporating dish (platinum or Pyrex) at a dropwise rate of about 2 milliliters per minute until the liquid surface reaches the top glass wool plug; then close the stopcock temporarily. Rinse the Pyrex flask which contained the filtrate with an additional 10-15 milliliters of heptane and add to the column. Wash (elute) the column with more heptane collecting about 100 milliliters of total eluate including that already collected in the evaporating dish. Evaporate the combined eluate in the evaporating dish to dryness on a steam bath. Dry the residue for 15 minutes in an oven maintained at a temperature of approximately 221 °F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram. Subtract the weight of the residue from the weight of chloroform-soluble extractives residue (') to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (e'). This e' is substituted for e in the equations in paragraph (d)(5)(i)(a) and (b) of this section.
 - (ii) For chloroform residues weighing more than 0.5 gram. Redissolve the dried and weighed chloroform-soluble extract residue as described in paragraph (d)(5)(iii)(b)(3)(i) of this section using proportionately larger quantities of heptane. Transfer the heptane solution to an appropriate-sized volumetric flask (i.e., a 250-milliliter flask for about 2.5 grams of residue) and adjust to volume with additional heptane. Pipette out an aliquot (about 50 milliliters) calculated to contain 0.1-0.5 gram of the chloroform-soluble extract residue and analyze

chromatographically as described in paragraph (d)(5)(iii)(b)(3)(i) of this section. In this case the weight of the dried residue from the heptane eluate must be multiplied by the dilution factor to obtain the weight of wax, petrolatum, and mineral oil residue to be subtracted from the weight of chloroform-soluble extractives residue (') to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (e'). This e' is substituted for e in the equations in paragraph (d)(5)(i)(a) and (b) of this section. (Note: In the case of chloroform-soluble extracts which contain high melting waxes (melting point greater than 170 °F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1-0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), table 1 under Category VIII.

[42 FR 14554, Mar. 15, 1977]

Editorial Note: For FEDERAL REGISTER citations affecting § 176.170, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.