

(d) The coating 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 the conditions of its intended use as shown in table 1 and 2 of §175.300(d) (using 20 percent alcohol as the solvent when the type of food contains approximately 20 percent alcohol) shall yield total extractives not to exceed those prescribed in §175.300(c)(3); lithium extractives not to exceed 0.025 milligram per square inch of surface; and chromium extractives not to exceed 0.05 microgram per square inch of surface.

(e) The coatings are used as food-contact surfaces for bulk reusable containers intended for storing, handling, and transporting food.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Subpart A [Reserved]

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

Sec.

- 176.110 Acrylamide-acrylic acid resins.
- 176.120 Alkyl ketene dimers.
- 176.130 Anti-offset substances.
- 176.150 Chelating agents used in the manufacture of paper and paperboard.
- 176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.
- 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
- 176.180 Components of paper and paperboard in contact with dry food.
- 176.200 Defoaming agents used in coatings.
- 176.210 Defoaming agents used in the manufacture of paper and paperboard.
- 176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.
- 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.
- 176.260 Pulp from reclaimed fiber.
- 176.300 Slimicides.
- 176.320 Sodium nitrate-urea complex.
- 176.350 Tamarind seed kernel powder.

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

SOURCE: 42 FR 14554, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 176 appear at 61 FR 14482, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; and 70 FR 72074, Dec. 1, 2005.

Subpart A [Reserved]

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

§ 176.110 Acrylamide-acrylic acid resins.

Acrylamide-acrylic acid resins may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Acrylamide-acrylic acid resins are produced by the polymerization of acrylamide with partial hydrolysis or by the copolymerization of acrylamide and acrylic acid.

(b) The acrylamide-acrylic acid resins contain less than 0.2 percent residual monomer.

(c) The resins are used as adjuvants in the manufacture of paper and paperboard in amounts not to exceed that necessary to accomplish the technical effect and not to exceed 2 percent by weight of the paper or paperboard.

§ 176.120 Alkyl ketene dimers.

Alkyl ketene dimers may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The alkyl ketene dimers are manufactured by the dehydrohalogenation of the acyl halides derived from the fatty acids of animal or vegetable fats and oils.

(b) The alkyl ketene dimers are used as an adjuvant in the manufacture of paper and paperboard under such conditions that the alkyl ketene dimers and their hydrolysis products dialkyl ketones do not exceed 0.4 percent by weight of the paper or paperboard.

(c) The alkyl ketene dimers may be used in the form of an aqueous emulsion which may contain sodium lignosulfonate as a dispersant.

§ 176.130 Anti-offset substances.

Substances named in paragraphs (b) and (c) of this section may be safely

Food and Drug Administration, HHS

§ 176.170

used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions of this section:

(a) The substances are applied to the nonfood contact, printed side of the paper or paperboard in an amount not greater than that required to accomplish the technical effect nor greater than any specific limitations, where such are provided.

(b) Anti-offset powders are prepared from substances that are generally recognized as safe in food, substances for which prior sanctions or approvals were granted and which are used in accordance with the specific provisions of such sanction or approval, and substances named in paragraph (c) of this section.

(c) The substances permitted are as follows:

Substances	Limitations
Carbon tetrachloride. Methyl hydrogen polysiloxanes. Industrial starch—modified Stannous oleate. Zinc-2-ethyl hexoate.	Complying with § 178.3520 of this chapter.

§ 176.150 Chelating agents used in the manufacture of paper and paperboard.

The substances named in paragraph (a) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

(a) Chelating agents:

List of substances	Limitations
Ammonium fructoheptonate. Ammonium glucoheptonate. Disodium ethylenediamine tetraacetate. Pentasodium salt of diethylenetriamine pentaacetate. Sodium fructoheptonate. Sodium glucoheptonate. Tetrasodium ethylenediamine tetraacetate. Trisodium <i>N</i> -hydroxyethyl ethylenediamine triacetate.	

(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required

to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

§ 176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.

The chromium (Cr III) complex of *N*-ethyl - *N* -heptadecylfluoro-octane sulfonyl glycine containing up to 20 percent by weight of the chromium (Cr III) complex of heptadecylfluoro-octane sulfonic acid may be safely used as a component of paper for packaging dry food when used in accordance with the following prescribed conditions.

(a) The food additive is used as a component of paper in an amount not to exceed 0.5 percent by weight of the paper.

(b)(1) The food-contact surface of the paper is overcoated with a polymeric or resinous coating at least 1/8-mil in thickness, that meets the provision of § 176.170; or

(2) The treated paper forms one or more plies of a paper in a multiwall bag and is separated from the food by at least one ply of packaging films or grease-resistant papers which serves as a functional barrier between the food additive and the food. Such packaging films or grease-resistant papers conform with appropriate food additive regulations.

(c) The labeling of the food additive shall contain adequate directions for its use to insure compliance with the requirements of paragraphs (a) and (b) of this section.

§ 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.

§ 176.170

21 CFR Ch. I (4–1–22 Edition)

(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 para-

graph (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.	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.
Acrylamide-β-methacryloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 10 molar percent of β-methacryloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
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 polymerization 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.	1. 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 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.

Food and Drug Administration, HHS

§ 176.170

List of Substances	Limitations
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 1 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 -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.
<i>tert</i> -Alkyl(C ₈ -C ₁₆)mercaptans	For use only as polymerization-control agent.
Aluminum acetate.	
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, and limited to use at a level not to exceed 2.5 percent by weight of coating solids.
Ammonium zirconium citrate (CAS Reg. No. 149564-62-5), ammonium zirconium lactate-citrate (CAS Reg. No. 149564-64-7), ammonium zirconium lactate (CAS Reg. No. 149564-63-6).	For use as insolubilizers with protein binders in coatings for paper and paperboard, at a level not to exceed 1.4 percent by weight of coating solids.
Anionic polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and 2,4-toluenediisocyanate with not more than 10 mole percent <i>N</i> -methylolpropanolamine and not less than 90 mole percent dimethylolpropionic acid. The final product is a 15 to 20 percent by weight aqueous solution, having a Brookfield viscosity of 25 to 100 centipoises at 24 °C (75 °F).	For use only as a surface sizing agent at a level not to exceed 0.1 percent by weight of dry paper and paperboard.
9,10-Anthraquinone (Chemical Abstracts Service Registry No. 84-65-1) which has a purity of not less than 98 percent.	For use only as a pulping aid in the alkaline pulping of lignocellulosic material at levels not to exceed 0.1 percent by weight of the raw lignocellulosic material.
Aromatic petroleum hydrocarbon resin, hydrogenated (CAS Reg. No. 88526-47-0), produced by the catalytic polymerization of aromatic substituted olefins from low boiling distillates of cracked petroleum stocks with a boiling point no greater than 220 °C (428 °F), and the subsequent catalytic reduction of the resulting aromatic 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 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 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 .	For use only as modifiers in wax polymer blend coatings for paper and paperboard at a level not to exceed 50 weight-percent of the coating solids under conditions of use E, F, and G identified in table 2 of paragraph (c) of this section.
Azo-bisobutyronitrile	For use only as polymerization catalyst.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)	For use only as a preservative in paper 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. Do.
Benzoyl peroxide	
<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.

List of Substances	Limitations
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 ₁₀ –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.
<i>tert</i> -Butyl hydroperoxide	For use only as polymerization catalyst.
<i>tert</i> -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 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.
<i>n</i> -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)carbamoil 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) (CAS Reg. No. 25136–75–8).	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.
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).	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.

List of Substances	Limitations
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.	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.
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.	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.
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.	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.
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 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).	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.
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-nitropropionamide (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 sheet-forming 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 using a No. 2 spindle at 12 r.p.m. (or by equivalent method).	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.
Diethylenetriamine	For use only as a modifier for amino resins.
<i>N,N</i> -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.

List of Substances	Limitations
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.
<i>N</i> -[(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.
<i>N,N</i> -Dioleylethylenediamine.	
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.	
<i>n</i> -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 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.
<i>n</i> -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 -diethylamino- ethyl chloride hydrochloride.	For use only as a retention aid and/or drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.

Food and Drug Administration, HHS

§ 176.170

List of Substances	Limitations
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.	For use only as a retention aid and/or internal size employed prior to the sheet-forming 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.
<i>N,N,N',N',N'',N''</i> -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).	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.
Hexamethylenetetramine	For use only as polymerization cross-linking agent for protein, including casein.
Hydroquinone and the monomethyl or monoethyl ethers of hydroquinone.	For use only as an inhibitor for monomers.
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).	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.
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.	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.
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.	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.
Imidazolium compounds, 2-(C ₁₇ and C ₁₇ -unsaturated alkyl)-1-[2-(C ₁₈ and C ₁₈ -unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS Reg. No. 72749–55–4)..	For use only at a level not to exceed 0.5 percent by weight of the dry paper and 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.
<i>N</i> -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.
<i>N</i> -methyl- <i>N</i> -(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.	

List of Substances	Limitations
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).	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.
Monoglyceride citrate.	
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.	
<i>N</i> -Oleoyl- <i>N</i> -stearylethylenediamine.	
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 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.	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.
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)acrylamide], 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 limited to use at a level not to exceed 0.09 mg/in ² of the finished paper and paperboard.

Food and Drug Administration, HHS

§ 176.170

List of Substances	Limitations
Poly[acrylamide-acrylic acid- <i>N</i> -(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).	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.
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.	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.
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-by-weight 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).	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.
Polyamide-epichlorohydrin water-soluble thermosetting resin (CAS Reg. No. 96387-48-3) prepared by reacting <i>N</i> -methyl-bis(3-aminopropyl) amine with oxalic acid and urea to form a basic polyamide and further reacting the polyamide with epichlorohydrin.	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.
Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid, isophthalic acid, itaconic acid or dimethyl glutarate with diethylenetriamine to form a basic polyamide and further reacting the polyamide with one of the following: Epichlorohydrin. Epichlorohydrin and ammonia mixture. Epichlorohydrin and sodium hydrosulfite mixture.	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 the paper or paperboard.
Polyamidoamine-ethyleneimine-epichlorohydrin resin prepared by reacting hexanedioic acid, <i>N</i> -(2-aminoethyl)-1,2-ethanediamine, (chloromethyl)oxirane, ethyleneimine (aziridine), and polyethylene glycol, partly neutralized with sulfuric acid (CAS Reg. No. 167678-45-7).	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.12 percent resin by weight of the finished dry paper or paperboard.
Polyamidol-epichlorohydrin modified resin produced by reacting glutaric acid dimethyl ester with diethylene-triamine to produce a basic polyamide which is modified by reaction with formaldehyde and further reacted with epichlorohydrin to form a water soluble cationic resin having a nitrogen content of 10.9-11.9 percent and a chlorine content of 13.8-14.8 percent, on a dry basis, and a minimum viscosity, in 12.5 percent by weight aqueous solution, of 10 centipoises at 25 °C., as determined by a Brookfield Model LVF viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method).	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 2.5 percent by weight of dry paper and paperboard fibers when such paper or paperboard is used in contact with food under conditions of use E through G described in table 2 of paragraph (c) of this section.
Polyamine-epichlorohydrin resin produced by the reaction of epichlorohydrin with monomethylamine to form a prepolymer and further reaction of this prepolymer with <i>N,N,N,N</i> -tetramethylethylenediamine such that the finished resin having a nitrogen content of 11.6 to 14.8 percent and a chlorine content of 20.8 to 26.4 percent and a minimum viscosity, in 25 percent by 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 flocculant, drainage aid, formation aid, retention aid, or strength additive employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.12 percent by weight of dry paper and paperboard fibers.

List of Substances	Limitations
Polyamine-epichlorohydrin resin produced by the reaction of <i>N,N</i> -dimethyl-1,3-propanediamine with epichlorohydrin and further reacted with sulfuric acid, Chemical Abstracts Service Registry Number [27029–41–0], such that the finished resin has a 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).	For use only as a clarifier in the treatment of influent water to be used in the manufacture of paper and paperboard, and used at a level not to exceed 20 parts per million of the influent water.
Polyamine-epichlorohydrin water-soluble thermosetting 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).	For use only as a wetstrength 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.
Polyamine-epichlorohydrin water-soluble thermosetting 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) 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).	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.
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).	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.
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 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).	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 to exceed 0.1 percent by weight of dry paper or paperboard fibers.
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).	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.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	For use only as provided in §§ 175.300, 178.3740 and 178.3860 of this chapter.

List of Substances	Limitations
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).	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.
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).	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.
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-by-weight aqueous solution of 2,000 centipoises at 25 °C., as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 60 r.p.m.	For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.
Polyester resin produced by reacting dimethylolpropionic acid (CAS Registry No. 4767-03-7) as a comonomer, at no more than 30 percent by weight of total polymer solids in reaction with 2,2-dimethyl-1,3-propanediol, phthalic anhydride and isophthalic acid, such that the polyester resin has a 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).	For use only as a surface-sizing compound applied after the sheet-forming operation in the manufacture of paper and paperboard and limited to use at levels not to exceed 0.1 percent by weight of finished dry paper or paperboard.
Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a) of this chapter.	For use only as component of coatings that 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.
Polyethylenamine mixture produced when 1 mole of ethylene dichloride, 1.05 moles of ammonia, and 2 moles of sodium hydroxide are made to react so that a 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.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
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 ethylenimine.	For use only as an adjuvant employed prior 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 anhydride adduct to diethanolamine is 1:1.	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.
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.	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.
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.	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.

List of Substances	Limitations
<p>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.</p> <p>Poly[oxyethylene (dimethyliminio) ethylene (dimethyliminio) ethylene dichloride] produced by reacting equimolar quantities of <i>N,N,N,N</i>-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 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:.</p> <p>Reduced viscosity in terms of deciliters per gram = $(t - t_0) / (t - C)$, where: <i>t</i> = Solution efflux time <i>t</i>₀ = Water efflux time <i>C</i> = Concentration of solution in terms of grams per deciliter</p> <p>Polypropylene glycol (minimum molecular weight 1,000). Potassium persulfate. 2-Propenoic acid, telomer with sodium 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propane sulfonate and sodium phosphinate (CAS Reg. No. 110224–99–2).</p> <p>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 Siloxanes (silicones), dimethyl, isopropyl methyl, methyl 1-methyl-C₉₋₄₉-alkyl (CAS Reg. No. 144635–08–5).</p> <p>Silver chloride-coated titanium dioxide</p> <p>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 <i>o</i>-phenylphenate solution. Sodium dioctyl sulfo succinate. Sodium formaldehyde sulfoxylate Sodium hypochlorite. Sodium <i>N</i>-methyl-<i>N</i>-oleyltaurate</p>	<p>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.</p> <p>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.</p> <p>For use only as a deposit control additive employed prior to the sheet forming operation in the manufacture of paper and paperboard and at a level not to exceed 0.15 percent by weight of the dry paper and paperboard.</p> <p>As provided in § 178.3870 of this chapter.</p> <p>For use only as a component of polyolefin 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).</p> <p>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.</p> <p>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.</p> <p>For use only as polymerization catalyst.</p> <p>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.</p>

Food and Drug Administration, HHS

§ 176.170

List of Substances	Limitations
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 sheet-forming 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. For use only in paper mill boilers.
Sodium poly(isopropenylphosphonate) (CAS Reg. No. 118632-18-1). Sodium zinc potassium polyphosphate (CAS Reg. No. 65997-17-3). Sperm oil, sulfated, ammonium, potassium, or sodium salt. Stannous oleate. Stearyl-2-lactylic acid and its calcium salt. Styrene-butadiene copolymers produced by copolymerizing styrene-butadiene with one or more of the monomers: acrylamide, acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, methacrylic acid, and <i>N</i> -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, ammonium sodium salt; having, in a 25 percent by weight aqueous solution at pH 8.8, a minimum viscosity of 600 centipoises at 25 °C as determined by Brookfield model LVT viscometer using a No. 3 spindle at 60 r.p.m. (or equivalent method). Styrene-maleic anhydride copolymer, sodium salt (minimum molecular weight 30,000).	For use only as a pigment dispersant in coatings at a level not to exceed 1 percent by weight of pigment.
Styrene-methacrylic acid copolymer, potassium salt (minimum molecular weight 30,000). Synthetic wax polymer prepared by the catalytic polymerization of alpha olefins such that the polymer has a maximum iodine number of 18 and a minimum number average molecular weight of 2,400.	For use only as a surface size at a level not to exceed 1 percent by weight of paper or paperboard substrate. For use only: 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. For use only as a coating thickening agent at a level not to exceed 1% by weight of coating solids. For use only as a component of petroleum wax and/or synthetic petroleum wax complying with § 178.3710 or § 178.3720 of 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. 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.
<i>N,N,N', N'</i> -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.

List of Substances	Limitations
Tetrasodium <i>N</i> - (1,2-dicarboxyethyl) - <i>N</i> - octadecylsulfo-succinate.	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 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.	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 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	Complying with § 178.3710 of this chapter.
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.	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	For use only as polymerization catalyst.
Zinc octoate.	
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 styrene 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.

List of substances	Limitations
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 <i>n</i> -alkanes in the range of C ₁₀ -C ₁₈ with not less than 50 percent C ₁₄ -C ₁₆)..	For use only: <ol style="list-style-type: none"> 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. 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.
2-Bromo-4'-hydroxyacetophenone	For use only as a preservative for coating formulations, binders, pigment slurries, and sizing solutions at a level not to exceed 0.006 percent by weight of the coating, solution, slurry or emulsion.
Butanedioic acid, sulfo-1,4-di-(C ₈ -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.
Butylbenzyl phthalate	Complying with § 178.3740 of this chapter.
Butyl oleate, sulfated, ammonium, potassium, or sodium salt. Butyraldehyde.	
Captan (N-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: <ol style="list-style-type: none"> 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 pigment slurries used as components of coatings for paper and paperboard intended for use in contact with food.

List of substances	Limitations
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. 2935–90–2). The mixture may contain magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	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 coating formulations and for additives used in the manufacture of paper and paperboard including fillers, binders, pigment slurries, and sizing solutions at a level not to exceed 25 parts per million (based on isothiazolone active ingredients) in the coating formulations and additives.
Copper 8-quinolinolate	For use only as preservative for coating formulations.
Cyclized rubber produced when natural pale crepe rubber dissolved in phenol is catalytically cyclized so that the finished cyclized rubber has a melting point of 145 °C to 155 °C as determined by ASTM method E28–67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," 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), and contains no more than 4000 ppm of residual-free phenol as determined by a gas liquid chromatographic procedure titled "Determination of Free Phenol in Cyclized Rubber Resin," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection 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 .	For use only in 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 VIII and IX.
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691–65–7) ..	For use only as a preservative at 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 phthalate.	
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 formulations.
Dimethylpolysiloxane, 100 centistokes viscosity.	
Dimethylpolysiloxane-beta-phenylethyl methyl polysiloxane copolymer (2:1), 200 to 400 centistokes viscosity.	
N,N'-Diphenyl-p-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 use F and G.
Disodium N-octadecylsulfosuccinamate	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.
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.

Food and Drug Administration, HHS

§ 176.170

List of substances	Limitations
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 starch- and 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.
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 1 α -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 (SiO ₂), 28 to 42 percent aluminum oxide (Al ₂ O ₃), and 2 to 7 percent of sodium oxide (Na ₂ O). 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 paper-board 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 paper-board.
Pentaerythritol tetrastearate.	

List of substances	Limitations
<p>Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, meeting the following specifications: Softening point 97 °C minimum, as determined by ASTM method E28–67 (Reapproved 1982), “Standard Test Method for Softening Point by Ring and Ball Apparatus;” aniline point 120 °C minimum, as determined by ASTM method D611–82, “Standard Test Methods for Aniline Point and Mixed Aniline Point of Petroleum Products and Hydrocarbon Solvents,” 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 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). Specific gravity 0.96–0.99 (20 °C/20 °C). Such petroleum hydrocarbon resins are produced by the catalytic polymerization of dienes and olefins from low-boiling distillates of cracked petroleum stocks that contain no material boiling over 200 °C and that meet the ultraviolet absorbance limits prescribed in § 172.880(b) of this chapter when subjected to the analytical 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 * * *”.</p> <p>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.</p> <p>Polyester resin produced by reacting the acid groups in montan wax with ethylene glycol.</p> <p>Polyethylene, oxidized</p> <p>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.</p> <p>Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt</p> <p>Polyoxypropylene-polyoxyethylene block polymers (minimum molecular weight 6,800).</p> <p>Polyvinyl acetate.</p> <p>Polyvinyl alcohol (minimum viscosity of 4% aqueous solution at 20 °C. of 4 centipoises).</p> <p>Polyvinyl butyral.</p> <p>Polyvinyl formal.</p> <p>Polyvinylidene chloride.</p> <p>Polyvinyl pyrrolidone.</p> <p>Polyvinyl stearate.</p> <p>Propylene glycol mono- and diesters of fats and fatty acids.</p> <p>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.</p>	<p>For use only as modifiers in waxpolymer blend coatings for corrugated paperboard intended for use in bulk packaging or raw fruits, raw vegetables, iced meat, iced fish, and iced poultry; and limited to use at a level not to exceed 30 weight-percent of the coating solids.</p> <p>Complying with § 177.1620 of this chapter.</p> <p>Not to exceed 300 p.p.m. in finished coated paper or paperboard.</p> <p>For use only as a surface coating. Platinum content not to exceed 200 parts per million.</p> <ol style="list-style-type: none"> 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 H described in table 2 of paragraph (c) of this section.

Food and Drug Administration, HHS

§ 176.170

List of substances	Limitations
Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg. No. 624-48-6), vinyl acetate (CAS Reg. No. 108-05-4), dibutyl maleate (CAS Reg. No. 105-76-0) and diallyl maleate (CAS Reg. No. 999-21-3) may be used as optional polymerization inhibitors. The polymer may also contain C ₁₆ -C ₁₈ olefins (CAS Reg. No. 68855-60-7) as a control release agent.	Platinum content not to exceed 100 parts per million. For use only as a release coating for pressure sensitive adhesives.
Sodium decylbenzenesulfonate. Sodium dihexyl sulfosuccinate. Sodium <i>n</i> -dodecylpolyethoxy (50 moles) sulfate-sodium isododecylphenoxyethoxy (40 moles) sulfate mixtures.	For use only as an 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 Sodium <i>o</i> -phenylphenate Sodium vinyl sulfonate polymerized. Sodium xylenesulfonate (CAS Reg. No. 1300-72-7)	For use only as preservative for coating formulations. Do. For use only in paper and paperboard coatings at levels not to exceed 0.01 percent by weight of the finished paper and paperboard.
Styrene copolymers produced by copolymerizing styrene with maleic anhydride and its methyl and butyl (<i>sec</i> - or <i>iso</i> -) esters. Such copolymers may contain β-nitrostyrene as a polymerization chain terminator.	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 (M _n) 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 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 weight percent of vinylidene chloride in the finished copolymers. The finished copolymers may contain not more than 10 weight percent of total polymer units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and/or methacrylic acid.	For use only as coatings or components of coatings.

List of substances	Limitations
Styrene-dimethylstyrene- α -methylstyrene copolymers produced by polymerizing equimolar ratios of the three comonomers such that the finished copolymers have a minimum average molecular weight of 835 as determined by ASTM method D2503–82, “Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermo-electric Measurement of Vapor Pressure,” 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 .	For use only in coatings for paper and paperboard intended for use in contact with nonfatty food and limited to use at a level not to exceed 50% by weight of the coating solids.
Styrene-isobutylene copolymers (weight average molecular weight not less than 6,300).	For use only in 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 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.	For use only as coatings or components of coatings.
2-Sulfoethyl methacrylate, sodium salt [Chemical Abstracts Service No. 1804–87–1].	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 coating.
α [<i>p</i> -(1,1,3,3-Tetramethylbutyl) phenyl]- ω -hydroxypoly (oxyethylene) hydrogen sulfate, sodium salt mixture with α -[<i>p</i> -(1,1,3,3-tetramethylbutyl)-phenyl]- ω -hydroxypoly (oxyethylene) with both substances having a poly(oxyethylene) content averaging 3 moles.	For use only as a surface-active agent at levels not to exceed 3 percent by weight of vinyl acetate polymer with ethylene and <i>N</i> -(hydroxymethyl) acrylamide intended for use 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 C, D, E, F, and G.
Tetrasodium <i>N</i> -(1,2-dicarboxyethyl)- <i>N</i> -octadecylsulfo-succinate.	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.	

List of substances	Limitations
<p>Vinyl acetate copolymers produced by copolymerizing vinyl acetate with one or more of the monomers acrylamide, acrylic acid, acrylonitrile, bicyclo-[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.</p> <p>Vinyl acetate polymer with ethylene and <i>N</i>-(hydroxymethyl) acrylamide containing not more than 6 weight percent of total polymer units derived from <i>N</i>-(hydroxymethyl) acrylamide.</p>	<p>For use only in coatings for paper and paperboard intended for use in contact with foods:</p> <ol style="list-style-type: none"> 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 C, D, E, F, and G.
<p>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-<i>n</i>-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 acid and/or maleic acid and/or their methyl, ethyl, propyl, butyl, amyl, heptyl, or octyl monoesters or from maleic anhydride or from mono-<i>n</i>-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-<i>n</i>-butyl ester of 5-norbornene-2,3-dicarboxylic acid).</p> <p>Vinyl chloride-vinyl acetate hydroxyl-modified copolymers.</p> <p>Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimellitic anhydride.</p> <p>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, methacrylic acid, methyl acrylate, methyl methacrylate, octadecyl methacrylate, propyl acrylate, 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.</p>	
<p>Colorants:</p> <p>Aluminum</p> <p>Aluminum hydrate</p> <p>Aluminum and potassium silicate (mica)</p> <p>Aluminum mono-, di-, and tristearate</p> <p>Aluminum silicate (China clay)</p> <p>Barium sulfate</p> <p>Bentonite</p> <p>Bentonite, modified with dimethyldioctadecylammonium ion</p> <p>Burnt umber</p>	<p>For use as a colorant only.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p> <p>Do.</p>

List of substances	Limitations
Calcium carbonate	Do.
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 silicate.	Do.
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

Condition of use	Types of food (see table 1)	Food-simulating solvents			
		Water	Heptane ¹	8 percent alcohol	50 percent alcohol
		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 hrdododo
	III, IV-A, VII-Ado	150 °F, 2 hrdodo
B. Boiling water sterilized	II, VII-B	212 °F, 30 min.dododo
	III, VII-Ado	120 °F, 30 min.dodo

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—Continued

Condition of use	Types of food (see table 1)	Food-simulating solvents			
		Water	Heptane ¹	8 percent alcohol	50 percent alcohol
		Time and temperature	Time and temperature	Time and temperature	Time and temperature
C. Hot filled or pasteurized above 150 °F	II, IV-B, VII-B	Fill boiling, cool to 100 °F.dododo
	III, IV-A, VII-Ado	120 °F, 15 min.dodo
D. Hot filled or pasteurized below 150 °F	V, IXdodododo
	II, IV-B, VI-B, VII-B	150 °F, 2 hrdododo
	III, IV-A, VII-Ado	100 °F, 30 min.dodo
	V, IXdodododo
E. Room temperature filled and stored (no thermal treatment in the container).	VI-Adodo	150 °F, 2 hrdo
	VI-Cdododo	150 °F, 2 hr.
	I, II, IV-B, VI-B, VII-B, III, IV-A, VII-A	120 °F, 24 hrdododo
	V, IXdo	70 °F, 30 min.dodo
F. Refrigerated storage (no thermal treatment in the container).	VI-Adodo	120 °F, 24 hrdo
	VI-Cdododo	120 °F, 24 hr.
	III, IV-A, VII-A	70 °F, 48 hr	70 °F, 30 min.dodo
	I, II, IV-B, VI-B, VII-B, VI-Adodo	70 °F, 48 hrdo
G. Frozen storage (no thermal treatment in the container).	VI-Cdododo	70 °F, 48 hr.
	I, II, IV-B, VII-B ..	70 °F, 24 hrdododo
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:	III, VII-Ado	70 °F, 30 min.dodo
	1. Aqueous or oil-in-water emulsion of high- or low-fat.	I, II, IV-B, VII-B ..	212 °F, 30 min.dodo
	2. Aqueous, high- or low-free oil or fat ..	III, IV-A, VII-A, IXdo	120 °F, 30 min.do

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 ex-

aggeration 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 2½-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 2½-inch-square samples from the formed paper or paperboard product to be tested.

(b) Carefully stack the eight 2½-inch-square samples and the five 2½-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, 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 (*e'*). This *e'* 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 (*e'*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* 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 milliliters 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.

Food and Drug Administration, HHS

§ 176.180

(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.

§ 176.180 Components of paper and paperboard in contact with dry food.

The substances listed 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, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in §176.170(c), table 1, under Type VIII, subject to the provisions of this section.

(a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.

(b) The substances permitted to be used include the following:

(1) Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

(2) Substances identified in the following list:

List of substances	Limitations
Acrylamide polymer with sodium 2-acrylamido-2-methylpropane-sulfonate (CAS Reg. No. 38193–60–1).	For use at a level not to exceed 0.015 weight percent of dry fiber.
(2-Alkenyl) succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 percent C ₃₀ and higher groups (CAS Reg. No. 70983–55–0).	
4-[2-(2-Alkoxy(C ₁₂ –C ₁₅) ethoxy) ethoxy]ethyl]disodium sulfosuccinate.	For use as a polymerization emulsifier and latex emulsion stabilizer at levels not to exceed 5 percent by weight of total emulsion solids.
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ –C ₁₈ with not less than 50 percent C ₁₄ –C ₁₆).	
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	Colorant.
Ammonium nitrate..	
Amylose..	
Barium metaborate	For use as preservative in coatings and sizings.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634–33–5)	For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.02 mg/in ² (0.0031 mg/cm ²) of finished paper and paperboard.
<i>N,N</i> -Bis(hydroxyethyl)lauramide.	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064–70–8	For use only as a preservative in coatings.
Borax	For use as preservative in coatings.
Boric acid	Do.
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.
<i>sec</i> -Butyl alcohol..	
Butyl benzyl phthalate..	
Candelilla wax..	
Carbon tetrachloride..	
Castor oil, polyoxyethylated (42 moles ethylene oxide)..	
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethylammonium chloride).	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Cationic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethyl-ammonium chloride).	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Chloral hydrate	Polymerization reaction-control agent.
<i>N</i> -Cyclohexyl- <i>p</i> -toluene sulfonamide..	

§ 176.180

21 CFR Ch. I (4-1-22 Edition)

List of substances	Limitations
2,5-Di- <i>tert</i> -butyl hydroquinone. Diethanolamine.. Diethylene glycol dibenzoate (CAS Reg. No. 120–55–8) Diethylene glycol monobutyl ether.. Diethylene glycol monoethyl ether.. Diethylenetriamine.. <i>N,N</i> -Diisopropanolamide of tallow fatty acids.. <i>N</i> -[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene.. <i>N,N</i> -Dioleoyl ethylenediamine, <i>N,N</i> -diilinooeyl-ethylenediamine, and <i>N</i> -oleoyl- <i>N</i> -linoleoyl-ethylenediamine mixture produced when tall oil fatty acids are made to react with ethylene-diamine such that the finished mixture has a melting point of 212°–228 °F, as determined by ASTM method D127–60, and an acid value of 10 maximum. ASTM Method D127–60 “Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax” (Revised 1960) is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection 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 .. Diphenylamine.. Dipropylene glycol dibenzoate (CAS Reg. No. 27138–31–4) Disodium <i>N</i> -octadecylsulfo succinamate.. <i>tert</i> -Dodecyl thioether of polyethylene glycol.. Erucamide (erucylamide).. Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-2(1 <i>H</i>)pyrimidinone, propoxylated.. Ethylene oxide Ethylene oxide adduct of mono-(2-ethylhexyl) o-phosphate.. Fatty acid (<i>C</i> ₁₂ – <i>C</i> ₁₈) diethanolamide.. Fish oil fatty acids, hydrogenated, potassium salt.. Formaldehyde.. Glyceryl monocaprate.. Glyceryl tribenzoate (CAS Reg. No. 614–33–5) Glyoxal.. Glyoxal-urea-formaldehyde condensate (CAS Reg. No. 27013–01–0) formed by reaction in the molar ratio of approximately 47:33:15, respectively. The reaction product has a number average molecular weight of 278±14 as determined by a suitable method.. Glyoxal-urea polymer (CAS Reg. No. 53037–34–6) Hexamethylenetetramine	For use only as a plasticizer in polymeric substances.
Hexylene glycol (2-methyl-2,4-pentanediol).. Hydroabietyl alcohol.. 5-Hydroxymethoxy methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-hydroxypoly-[methyleneoxy]methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane mixture.. Imidazolium compounds, 2–(<i>C</i> ₁₇ and <i>C</i> ₁₇ -unsaturated alkyl)-1-[2–(<i>C</i> ₁₈ and <i>C</i> ₁₈ -unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS Reg. No. 72749–55–4).. Isopropanolamine hydrochloride.. Isopropyl <i>m</i> - and <i>p</i> -cresol (thymol derived).. Itaconic acid.. Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt.. Melamine-formaldehyde modified with: Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl). Diethylenetriamine.. Imino-bis-butylamine.. Imino-bis-ethyleneimine.. Imino-bis-propylamine.. Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane. Sulfanilic acid.. Tetraethylenepentamine.. Triethylenetetramine.. Methyl alcohol..	For use only as a plasticizer in polymeric substances.
	Fumigant in sizing.
	For use only as a plasticizer in polymeric coatings.
	For use as an insolubilizer for starch in coatings.
	For use as an insolubilizer for starch.
	Polymerization crosslinking agent for protein, including casein. As neutralizing agent with myristochromic chloride complex and stearato-chromic chloride complex.
	For use only as an antibacterial preservative.
	For use only at levels not to exceed 0.5 percent by weight of the dry paper and paperboard.
	Basic polymer.

Food and Drug Administration, HHS

§ 176.180

List of substances	Limitations
Methyl ethers of mono-, di-, and tripropylene glycol..	
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt..	
Methylated poly(<i>N</i> -1,2-dihydroxyethylene-1,3-imidazolidin-2-one).	For use only as an in solubilizer for starch.
Modified polyacrylamide resulting from an epichlorohydrin addition to a condensate of formaldehyde-dicyandiamide-diethylene triamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25 °C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method).	For use only as a dry strength and pigment retention aid agent 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 fibers.
Mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of C ₁₅ -C ₂₁ groups.	For use only as an emulsifier.
Monoglyceride citrate..	
Myristic chromic chloride complex..	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt..	
Nickel..	
β-Nitrostyrene	Basic polymer.
Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea (CAS Reg. No. 68412-14-6), and the acetate salts thereof (CAS Reg. No. 68784-21-4), which may be emulsified with ethoxylated tallow alkyl amines (CAS Reg. No. 61791-26-2).	For use prior to sheet forming at levels not to exceed 12 pounds per ton of paper.
α- <i>cis</i> -9-Octadecenyl- <i>omega</i> -hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles..	
α-(<i>p</i> -Nonylphenyl)- <i>omega</i> -hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles..	
Oleic acid reacted with <i>N</i> -alkyl-(C ₁₆ -C ₁₈) trimethylenediamine..	
Oxidized soy isolate having 50 to 70 percent of its cystine residues oxidized to cysteic acid.	For use as a binder adhesive component of coatings.
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in § 176.170(b)(2).	For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings.
Petroleum hydrocarbon resins (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks)..	
Petroleum hydrocarbons, light and odorless..	
<i>o</i> -Phthalic acid modified hydrolyzed soy protein isolate..	
Pine oil..	
Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) complying with the identity described in § 176.170(a)..	
Polyamide-epichloro hydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetriamine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11–15 percent and chlorine level of 20–23 percent on a dry basis..	
Polyamide-ethyleneimine-epichlorohydrin resin is prepared by reacting equimolar amounts of adipic acid and three amines (21 mole percent of 1,2-ethanediamine, 51 mole percent of <i>N</i> -(2-aminoethyl)-1,3-propanediamine, and 28 mole percent of <i>N</i> , <i>N</i> '-1,2-ethanediylbis(1,3-propanediamine)) to form a basic polyamidoamine which is modified by reaction with ethyleneimine (5.5:1.0 ethyleneimine:polyamidoamine). The modified polyamidoamine is reacted with a crosslinking agent made by condensing approximately 34 ethylene glycol units with (chloromethyl)oxirane, followed by pH adjustment with formic acid or sulfuric acid to provide a finished product as a formate (CAS Reg. No. 114133-44-7) or a sulfate (CAS Reg. No. 167678-43-5), having a weight-average molecular weight of 1,300,000 and a number-average molecular weight of 16,000..	

List of substances	Limitations
<p>Polyamide-ethyleneimine-epichlorohydrin resin (CAS Reg. No. 115340–77–7), prepared by reacting equimolar amounts of adipic acid and <i>N</i>-(2-aminoethyl)-1,2-ethanediamine to form a basic polyamidoamine which is modified by reaction with ethyleneimine, and further reacted with formic acid and (chloromethyl)oxirane-α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl)..</p> <p>Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter..</p> <p>Poly [2-(diethylamino) ethyl methacrylate] phosphate..</p> <p>Polyethylene glycol (200) dilaurate..</p> <p>Polyethylene glycol monoisotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413–26–6).</p> <p>Polymers: Homopolymers and copolymers of the following monomers:</p> <p>Acrylamide.</p> <p>Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters.</p> <p>Acrylonitrile.</p> <p>Butadiene.</p> <p>Crotonic acid.</p> <p>Cyclol acrylate.</p> <p>Decyl acrylate.</p> <p>Diallyl fumarate.</p> <p>Diallyl maleate.</p> <p>Diallyl phthalate.</p> <p>Dibutyl fumarate.</p> <p>Dibutyl itaconate.</p> <p>Dibutyl maleate.</p> <p>Di(2-ethylhexyl) maleate.</p> <p>Dioctyl fumarate.</p> <p>Dioctyl maleate.</p> <p>Divinylbenzene.</p> <p>Ethylene.</p> <p>2-Ethylhexyl acrylate.</p> <p>Fumaric acid.</p> <p>Glycidyl methacrylate.</p> <p>2-Hydroxyethyl acrylate.</p> <p><i>N</i>-(Hydroxymethyl) acrylamide.</p> <p>Isobutyl acrylate.</p> <p>Isobutylene.</p> <p>Isoprene.</p> <p>Itaconic acid.</p> <p>Maleic anhydride and its methyl or butyl esters.</p> <p>Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.</p> <p>Methylstyrene.</p> <p>Mono(2-ethylhexyl) maleate.</p> <p>Monoethyl maleate.</p> <p>5-Norbornene-2,3-dicarboxylic acid, mono-<i>n</i>-butyl ester.</p> <p>Styrene.</p> <p>Vinyl acetate.</p> <p>Vinyl butyrate.</p> <p>Vinyl chloride.</p> <p>Vinyl crotonate.</p> <p>Vinyl hexoate.</p> <p>Vinylidene chloride.</p> <p>Vinyl pelargonate.</p> <p>Vinyl propionate.</p> <p>Vinyl pyrrolidone.</p> <p>Vinyl stearate.</p> <p>Vinyl sulfonic acid.</p> <p>Polymer prepared from urea, ethanedial, formaldehyde, and propionaldehyde (CAS Reg. No. 106569–82–8).</p> <p>Polyoxyethylene (minimum 12 moles) ester of tall oil (30%–40% rosin acids)..</p> <p>Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,900)..</p> <p>Polyvinyl alcohol..</p> <p>Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20–0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of $K_2Ti_4O_9$ and $K_2Ti_6O_{13}$..</p>	<p>For use only as a surfactant at levels not to exceed 3 percent in latex formulations used in pigment binders for paper and paperboard.</p> <p>Basic polymer.</p> <p>For use only as a starch and protein reactant in paper and paperboard coatings.</p>

Food and Drug Administration, HHS

§ 176.200

List of substances	Limitations
<p>Sodium diisobutylphenoxy diethoxyethyl sulfonate..</p> <p>Sodium diisobutylphenoxy monoethoxy ethylsulfonate..</p> <p>Sodium <i>n</i>-dodecylpolyethoxy (50 moles) sulfate..</p> <p>Sodium isododecylphenoxy polyethoxy (40 moles) sulfate..</p> <p>Sodium <i>N</i>-methyl-<i>N</i>-oleyl taurate..</p> <p>Sodium methyl silicate..</p> <p>Sodium nitrite..</p> <p>Sodium polyacrylate..</p> <p>Sodium bis-tridecylsulfosuccinate..</p> <p>Sodium xylene sulfonate..</p> <p>Stearato chromic chloride complex..</p> <p>Styrene-allyl alcohol copolymers..</p> <p>Styrene-methacrylic acid copolymer, potassium salt..</p> <p>Tetraethylenepentamine</p> <p>α-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl]-<i>omega</i>-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles..</p> <p>α-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl or <i>p</i>-nonylphenyl]-<i>omega</i>-hydroxypoly(oxyethylene) where nonyl group is a propylene trimer isomer..</p> <p>Tetrasodium <i>N</i>-(1,2-dicarboxyethyl)-<i>N</i>-octadecyl sulfosuccinamate..</p> <p>Toluene..</p> <p>Triethanolamine..</p> <p>Triethylenetetramine</p> <p>Triethylenetetramine monoacetate, partially stearylated..</p> <p>Urea-formaldehyde chemically modified with:</p> <p>Alcohol (methyl, ethyl, butyl, isobutyl, propyl, or isopropyl).</p> <p>Aminomethylsulfonic acid.</p> <p>Diaminobutane.</p> <p>Diaminopropane.</p> <p>Diethylenetriamine.</p> <p><i>N,N</i>-Dioleylethylenediamine.</p> <p>Diphenylamine.</p> <p><i>N,N</i>-Distearoylethylenediamine.</p> <p>Ethylenediamine.</p> <p>Guanidine.</p> <p>Imino-bis-butylamine.</p> <p>Imino-bis-ethylamine.</p> <p>Imino-bis-propylamine.</p> <p><i>N</i>-Oleoyl-<i>N</i>-stearoylethylenediamine.</p> <p>Polyamines made by reacting ethylenediamine or triethylenediamine with dichloroethane or dichloropropane.</p> <p>Tetraethylenepentamine.</p> <p>Triethylenetetramine.</p> <p>Xylene..</p> <p>Xylene sulfonic acid-formaldehyde condensate, sodium salt..</p> <p>Zinc stearate..</p>	<p>Polymerization cross-linking agent.</p> <p>Polymerization cross-linking agent.</p>

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 176.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 176.200 Defoaming agents used in coatings.

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.

§ 176.200

21 CFR Ch. I (4–1–22 Edition)

(c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the formulation of defoaming agents include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in defoaming agents and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	Limitations
<p><i>n</i>-Butyl alcohol. tert-Butyl alcohol. Butyl stearate. Castor oil, sulfated, ammonium, potassium, or sodium salt. Cetyl alcohol. Cyclohexane. Cyclohexanol. Diethylene glycol monolaurate. Diethylene glycol monostearate. Dimers and trimers of unsaturated C₁₈ fatty acids derived from:</p> <p style="padding-left: 40px;">Animal and vegetable fats and oils. Tall oil.</p> <p>Dimethylpolysiloxane. α-(Dinonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl), containing 7 to 24 moles of ethylene oxide per mole of dinonylphenol (CAS Reg. No. 9014–93–1). Dipropylene glycol. Ethyl alcohol. Fats and oils derived from animal, marine, or vegetable sources: Fatty acids derived from animal, marine, or vegetable fats and oils, and salts of such acids, single or mixed, as follows:</p> <p style="padding-left: 80px;">Aluminum.. Ammonium.. Calcium.. Magnesium.. Potassium.. Sodium.. Zinc..</p> <p>Formaldehyde Glyceryl mono-12-hydroxystearate. Glyceryl monostearate. Hexane. Hexylene glycol (2-methyl-2,4-pentanediol). Isobutyl alcohol. Isopropyl alcohol. Kerosene. Lecithin hydroxylated. Methyl alcohol. Methylcellulose. Methyl esters of fatty acids derived from animal, marine, or vegetable fats and oils. Methyl oleate. Methyl palmitate. Mineral oil. Mustardseed oil, sulfated, ammonium, potassium, or sodium salt. Myristyl alcohol. Naphtha. β-Naphthol Nonylphenol. Odorless light petroleum hydrocarbons Oleic acid, sulfated, ammonium, potassium, or sodium salt. Parachlorometacresol Peanut oil, sulfated, ammonium, potassium, or sodium salt. Petrolatum. Pine oil. Polyacrylic acid, sodium salt Polyethylene.</p>	<p>For use only at levels not to exceed 0.1% by weight of total coating solids.</p> <p>For use only in defoaming agents for the production of styrene-butadiene coatings at a level not to exceed 0.05 percent by weight of the finished coating.</p> <p>For use as preservative of defoamer only.</p> <p>For use as preservative of defoamer only.</p> <p>As defined in § 178.3650 of this chapter.</p> <p>For use as preservative of defoamer only.</p> <p>As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane.</p>

List of substances	Limitations
Polyethylene, oxidized. Polyethylene glycol (200) dilaurate. Polyethylene glycol (400) dioleate. Polyethylene glycol (600) dioleate. Polyethylene glycol (400) esters of coconut oil fatty acids. Polyethylene glycol (400) monooleate. Polyethylene glycol (600) monooleate. Polyethylene glycol (600) monoricinoleate. Polyethylene glycol (400) monostearate. Polyoxybutylene-polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 3,700). Polyoxyethylated (min. 3 mols) cetyl alcohol. Polyoxyethylated (min. 5 mols) oleyl alcohol. Polyoxyethylated (min. 1.5 mols) tridecyl alcohol. Polyoxyethylene (min. 15 mols) ester of rosin. Polyoxyethylene (min. 8 mols) monooleate. Polyoxyethylene (40) stearate. Polyoxypropylated (min. 20 mols) butyl alcohol. Polyoxypropylene glycol (min. mol. wt. 200). Polyoxypropylene (min. 20 mols) oleate butyl ether. Polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 1,900). Polyoxypropylene (min. 40 mols) stearate butyl ether. Potassium pentachlorophenate Potassium trichlorophenate Propylene glycol monoester of soybean oil fatty acids. Propylene glycol monoester of tallow fatty acids. Ricebran oil, sulfated, ammonium, potassium, or sodium salt. Rosins and rosin derivatives Silica. Sodium 2-mercaptobenzothiazole Sodium pentachlorophenate Sodium trichlorophenate Sperm oil, sulfated, ammonium, potassium, or sodium salt. Stearyl alcohol. Tall oil fatty acids. Tallow fatty acids, hydrogenated or sulfated. Tallow, sulfated, ammonium, potassium, or sodium salt. Triethanolamine. Triisopropanolamine. Waxes, petroleum.	For use as preservative of defoamer only. Do. As provided in § 178.3870 of this chapter. For use as preservative of defoamer only. Do. Do.

(e) The defoaming agents are used as follows:

(1) The quantity of defoaming agent or agents used shall not exceed the amount reasonably required to accomplish the intended effect, which is to prevent or control the formation of foam.

(2) The defoaming agents are used in the preparation and application of coatings for paper and paperboard.

[42 FR 14554, Mar. 15, 1977, as amended at 62 FR 39772, July 24, 1997]

§ 176.210 Defoaming agents used in the manufacture of paper and paperboard.

Defoaming agents may be safely used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The defoaming agents are prepared from one or more of the substances named in paragraph (d) of this section, subject to any prescribed limitations.

(b) The defoaming agents are used to prevent or control the formation of foam during the manufacture of paper and paperboard prior to and during the sheet-forming process.

(c) The quantity of defoaming agent or agents added during the manufacturing process shall not exceed the amount necessary to accomplish the intended technical effect.

(d) Substances permitted to be used in the formulation of defoaming agents include substances subject to prior sanctions or approval for such use and employed subject to the conditions of such sanctions or approvals, substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard,

§ 176.210

and substances listed in this paragraph, subject to the limitations, if any, prescribed.

(1) Fatty triglycerides, and the fatty acids, alcohols, and dimers derived therefrom:

Beef tallow.
Castor oil.
Coconut oil.
Corn oil.
Cottonseed oil.
Fish oil.
Lard oil.
Linseed oil.
Mustardseed oil.
Palm oil.
Peanut oil.
Rapeseed oil.
Ricebran oil.
Soybean oil.
Sperm oil.
Tall oil.

(2) Fatty triglycerides, and marine oils, and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses:

Aluminum hydroxide (soaps).
Ammonia (amides).
Butanol (esters).
Butoxy-polyoxypropylene, molecular weight 1,000-2,500 (esters).
Butylene glycol (esters).
Calcium hydroxide (soaps).
Diethanolamine (amides).
Diethylene glycol (esters).
Ethylene glycol (esters).
Ethylene oxide (esters and ethers).
Glycerin (mono- and diglycerides).
Hydrogen (hydrogenated compounds).
Hydrogen (amines).
Isobutanol (esters).
Isopropanol (esters).
Magnesium hydroxide (soaps).
Methanol (esters).
Morpholine (soaps).
Oxygen (air-blown oils).
Pentaerythritol (esters).
Polyoxyethylene, molecular weights 200, 300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters).
Polyoxypropylene, molecular weight 200-2,000 (esters).
Potassium hydroxide (soaps).
Propanol (esters).
Propylene glycol (esters).
Propylene oxide (esters).
Sodium hydroxide (soaps).
Sorbitol (esters).
Sulfuric acid (sulfated and sulfonated compounds).

21 CFR Ch. I (4-1-22 Edition)

Triethanolamine (amides and soaps).
Triisopropanolamine (amides and soaps).
Trimethylolethane (esters).
Zinc hydroxide (soaps).

(3) Miscellaneous:

Alcohols and ketone alcohols mixture (still-bottom product from C₁₂-C₁₈ alcohol manufacturing process).
Amyl alcohol.
Butoxy polyethylene polypropylene glycol molecular weight 900-4,200.
Butoxy-polyoxypropylene molecular weight 1,000-2,500.
Butylated hydroxyanisole.
Butylated hydroxytoluene.
Calcium lignin sulfonate.
Capryl alcohol.
p-Chlorometacresol.
Cyclohexanol.
Diacetyltartaric acid ester of tallow monoglyceride.
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7), for use as a preservative at a level not to exceed 0.05 weight-percent of the defoaming agent.
Diethanolamine.
Diethylene triamine.
Di-(2-ethylhexyl) phthalate.
2,6-Dimethyl heptanol-4 (nonyl alcohol).
Dimethylpolysiloxane.
Di-*tert*-butyl hydroquinone.
Dodecylbenzene sulfonic acids.
Ethanol.
2-Ethylhexanol.
Ethylenediamine tetraacetic acid tetrasodium salt.
Formaldehyde.
Heavy oxo-fraction (a still-bottom product of iso-octyl alcohol manufacture, of approximate composition: Octyl alcohol 5 percent, nonyl alcohol 10 percent, decyl and higher alcohols 35 percent, esters 45 percent, and soaps 5 percent).
2-Heptadecenyl-4-methyl-4-hydroxymethyl-2-oxazoline.
Hexylene glycol (2-methyl-2,4-pentanediol).
12-Hydroxystearic acid.
Isobutanol.
Isopropanol.
Isopropylamine salt of dodecylbenzene sulfonic acid.
Kerosine.
Lanolin.
Methanol.
Methyl 12-hydroxystearate.
Methyl taurine-oleic acid condensate, molecular weight 486.
a,a'-[Methylenebis[4-(1,1,3,3-tetramethylbutyl)-*o*-phenylene]]bis[*omega*-hydroxypoly(oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.
Mineral oil.
Mono-, di-, and triisopropanolamine.
Mono- and diisopropanolamine stearate.
Monobutyl ether of ethylene glycol.
Monoethanolamine.

Morpholine.
 Myristyl alcohol.
 Naphtha.
 β -Naphthol.
 Nonylphenol.
 Odorless light petroleum hydrocarbons.
 Oleyl alcohol.
 Petrolatum.
o-Phenylphenol.
 Pine oil.
 Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.
 Polyethylene.
 Polyethylene, oxidized (air-blown).
 Polymer derived from *N*-vinyl pyrrolidone and copolymers derived from the mixed alkyl (C₁₂-C₁₅, C₁₆, C₁₈, C₂₀, and C₂₂) methacrylate esters, butyl methacrylate (CAS Reg. No. 97-88-1), isobutyl methacrylate (CAS Reg. No. 97-86-9) and methyl methacrylate (CAS Reg. No. 80-62-6); the combined polymer contains no more than 5 weight percent of polymer units derived from *N*-vinyl pyrrolidone and is present at a level not to exceed 7 parts per million by weight of the finished dry paper and paperboard fibers.
 Polyoxyethylene (4 mols) decyl phosphate.
 Polyoxyethylene (4 mols) di(2-ethyl hexanoate).
 Polyoxyethylene (15 mols) ester of rosin.
 Polyoxyethylene (3-15 mols) tridecyl alcohol.
 Polyoxypropylene, molecular weight 200-2,000.
 Polyoxypropylene-polyoxethylene condensate, minimum molecular weight 950.
 Polyoxypropylene-ethylene oxide condensate of ethylene diamine, molecular weight 1,700-3,800.
 Polyvinyl pyrrolidone, molecular weight 40,000.
 Potassium distearyl phosphate.
 Potassium pentachlorophenate.
 Potassium trichlorophenate.
 Rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter.
 Silica.
 Siloxanes and silicones, dimethyl, methylhydrogen, reaction products with polyethylene-polypropylene glycol monoallyl ether (CAS Reg. No. 71965-38-3).
 Sodium alkyl (C₉-C₁₅) benzene-sulfonate.
 Sodium dioctyl sulfosuccinate.
 Sodium distearyl phosphate.
 Sodium lauryl sulfate.
 Sodium lignin sulfonate.
 Sodium 2-mercaptobenzothiazole.
 Sodium naphthalenesulfonic acid (3 mols) condensed with formaldehyde (2 mols).
 Sodium orthophenylphenate.
 Sodium pentachlorophenate.
 Sodium petroleum sulfonate, molecular weight 440-450.
 Sodium trichlorophenate.
 Stearyl alcohol.

α -[*p*-(1,1,3,3-Tetramethylbutyl) phenyl-, *p*-nonylphenyl-, or *p*-dodecylphenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-alkylphenol (alkyl group is 1,1,3,3-tetramethylbutyl, a propylene trimer isomer, or a propylene tetramer isomer) with an average of 1.5-15 moles of ethylene oxide.
 Tetrahydrofurfuryl alcohol.
 Tributyoxyethyl phosphate.
 Tributyl phosphate.
 Tridecyl alcohol.
 Triethanolamine.
 Triethylene glycol di(2-ethyl hexanoate).
 Tri-(2-ethylhexyl) phosphate.
 Tristearyl phosphate.
 Wax, petroleum, Type I and Type II.
 Wax, petroleum (oxidized).
 Wax (montan).

[42 FR 14554, Mar. 15, 1977, as amended at 47 FR 17986, Apr. 27, 1982; 47 FR 46495, Oct. 19, 1982; 47 FR 56845, Dec. 21, 1982; 54 FR 24897, June 12, 1989; 57 FR 31313, July 15, 1992; 61 FR 14246, Apr. 1, 1996]

§ 176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.

3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione may safely be used as a preservative in the manufacture and coating of paper and paperboard intended for use in contact with food in accordance with the following prescribed conditions:

(a) It is used as follows:

(1) In the manufacture of paper and paperboard as a preservative for substances added to the pulp suspension prior to the sheet-forming operation provided that the preservative is volatilized by heat in the drying and finishing of the paper and paperboard.

(2) As a preservative for coatings for paper and paperboard, *Provided*, That the preservative is volatilized by heat in the drying and finishing of the coated paper or paperboard.

(b) The quantity used shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any physical or technical effect in the food itself.

(c) The use of a preservative in any substance or article subject to any regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications and limitations prescribed by such regulation for the substance or article.

§ 176.250

21 CFR Ch. I (4–1–22 Edition)

§ 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.

Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane may be safely used as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food in an amount not to exceed that necessary to accomplish the intended physical or technical effect and not to exceed 6 pounds per ton of finished paper or paperboard.

§ 176.260 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in paragraphs (b)(1) and (2) of this section, by repulping with water to recover the fiber with the least possible amount of nonfibrous substances.

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears

or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

§ 176.300 Slimicides.

(a) Slimicides may be safely used in the manufacture of paper and paperboard that contact food, in accordance with the following prescribed conditions:

(1) Slimicides are used as antimicrobial agents to control slime in the manufacture of paper and paperboard.

(2) Subject to any prescribed limitations, slimicides are prepared from one or more of the slime-control substances named in paragraph (c) of this section to which may be added optional adjunct substances as provided for under paragraph (d) of this section.

(3) Slimicides are added to the process water used in the production of paper or paperboard, and the quantity added shall not exceed the amount necessary to accomplish the intended technical effect.

(b) To insure safe usage, the label or labeling of slimicides shall bear adequate directions for use.

(c) Slime-control substances permitted for use in the preparation of slimicides include substances subject to prior sanction or approval for such use and the following:

List of substances	Limitations
Acrolein.	
Alkenyl (C ₁₆ -C ₁₈) dimethylethyl-ammonium bromide.	
<i>n</i> -Alkyl (C ₁₂ -C ₁₈) dimethyl benzyl ammonium chloride.	
1,2-Benzisothiazolin-3-one	At a level of 0.06 pound per ton of dry weight fiber.
Bis(1,4-bromoacetoxymethyl)-2-butene.	
5,5-Bis(bromoacetoxymethyl) <i>m</i> -dioxane.	
2,6-Bis(dimethylaminomethyl) cyclohexanone.	
1,2-Bis(monobromoacetoxymethyl) ethane [CA Reg. No. 3785–34–0]	At a maximum level of 0.10 pound per ton of dry weight fiber.
Bis(trichloromethyl)sulfone.	
4-Bromoacetoxymethyl- <i>m</i> -dioxolane.	
2-Bromo-4'-hydroxyacetophenone.	
2-Bromo-2-nitropropane-1,3-diol (CAS Reg. No. 52–51–7)	At a maximum level of 0.6 pound per ton of dry weight fiber.
β-Bromo-β-nitrostyrene	At a maximum level of 1 pound per ton of dry weight fiber.
Chloroethylenebisithiocyanate.	
5-Chloro-2 - methyl - 4 - isothiazolin-3-one calcium chloride and 2-methyl-4-isothiazolin-3-one calcium chloride mixture at a ratio of 3 parts to 1 part.	At a level of 2.5 pounds per ton of dry weight fiber.
Chlorinated levulinic acids.	
Chloromethyl butanethiolsulfonate.	
Cupric nitrate.	

Food and Drug Administration, HHS

§ 176.300

List of substances	Limitations
<i>n</i> -Dialkyl (C ₁₂ -C ₁₈) benzylmethylammonium chloride.	
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7) ..	At a maximum level of 0.005% of dry weight fiber.
2,2-Dibromo-3-nitropropionamide	At a maximum level of 0.1 lb/ton of dry weight fiber.
2,3-Dibromopropionaldehyde.	
4,5-dichloro-1, 2-dithiol-3-one (CAS Reg. No. 1192-52-5)	For use only at levels not to exceed 10 milligrams per kilogram in the pulp slurry.
1,3-Dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) that may contain no more than 20 weight percent 1,3-dihalo-5-ethyl-5-methylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine)..	At a maximum level of 1.0 kilogram (kg) per 1,000 kg of dry weight fiber.
4-(Diiodomethylsulfonyl) toluene (CAS Reg. No. 20018-09-1).	At a maximum level of 0.2 pound per ton (100 grams/1,000 kilograms) of dry weight fiber.
3,5-Dimethyl 1,3,5,2 <i>H</i> -tetrahydrothiadiazine-2-thione.	
Dipotassium and disodium ethylenebis(dithiocarbamate).	
Disodium cyanodithioimidocarbonate.	
<i>n</i> -Dodecylguanidine hydrochloride	At a maximum level of 0.20 pound per ton of dry weight fiber.
Glutaraldehyde (CAS Reg. No. 111-30-8).	
2-(<i>p</i> -hydroxyphenyl) glyoxylohydroximoyl chloride (CAS Registry No. 34911-46-1).	At a level of 0.02 pound per ton of dry weight fiber.
2-Hydroxypropyl methanethiol sulfonate.	
2-Mercaptobenzothiazole.	
Methylenebisbutanethiolsulfonate.	
Methylenebisithiocyanate.	
2-Nitrobutyl bromoacetate [CA Reg. No. 32815-96-6]	At a maximum level of 0.15 pound per ton of dry weight fiber.
N-[α -(Nitroethyl)benzyl] ethylenediamine.	
Potassium 2-mercaptobenzothiazole.	
Potassium <i>N</i> -hydroxymethyl- <i>N</i> -methylthiocarbamate.	
Potassium <i>N</i> -methylthiocarbamate.	
Potassium pentachlorophenate.	
Potassium trichlorophenate.	
Silver fluoride	Limit of addition to process water not to exceed 0.024 pound, calculated as silver fluoride, per ton of paper produced.
Silver nitrate.	
Sodium dimethyldithiocarbamate.	
Sodium 2-mercaptobenzothiazole.	
Sodium pentachlorophenate.	
Sodium trichlorophenate.	
1,3,6,8-Tetraazatricyclo[6.2.1.1 ^{3,6}] dodecane.	
3,3,4,4-Tetrachlorotetrahydrothiophene-1,1-dioxide.	
Tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566-30-8).	Maximum use level of 84 mg/kg in the pulp slurry. The additive may also be added to water, which when introduced into the pulp slurry, results in a concentration in the pulp slurry not to exceed 84 mg/kg.
2-(Thiocyanomethylthio) benzothiazole.	
Vinylene bithiocyanate.	

(d) Adjuvant substances permitted to be used in the preparation of slimicides include substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, substances permitted to be used in paper and paperboard by other regulations in this chapter, and the following:

Acetone.
Butylene oxide.
Dibutyl phthalate.
Didecyl phthalate.
N,N-Dimethylformamide.
Dodecyl phthalate.
Ethanolamine.
Ethylene glycol.
Ethylenediamine.
N-methyl-2-pyrrolidone (CAS Reg. No. 872-50-4).

α,α' -[Methylenebis[4-(1,1,3,3-tetramethylbutyl)-*o*-phenylene]] *bis*[*omega*-hydroxypoly(oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.
Monomethyl ethers of mono-, di-, and tripropylene glycol.
Nonylphenol reaction product with 9 to 12 molecules of ethylene oxide.
Octylphenol reaction product with 25 molecules of propylene oxide and 40 molecules of ethylene oxide.

[42 FR 14554, Mar. 15, 1977, as amended at 42 FR 41854, Aug. 19, 1977; 44 FR 75627, Dec. 21, 1979; 46 FR 36129, July 14, 1981; 49 FR 5748, Feb. 15, 1984; 51 FR 19059, May 27, 1986; 51 FR 43734, Dec. 4, 1986; 54 FR 18103, Apr. 27, 1989; 55 FR 31825, Aug. 6, 1990; 64 FR 46130, Aug. 24, 1999; 64 FR 69900, Dec. 15, 1999; 65 FR 40497, June 30, 2000; 65 FR 70790, Nov. 28, 2000; 69 FR 24512, May 4, 2004]

§ 176.320

§ 176.320 Sodium nitrate-urea complex.

Sodium nitrate-urea complex may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Sodium nitrate-urea complex is a clathrate of approximately two parts urea and one part sodium nitrate.

(b) Sodium nitrate-urea complex conforming to the limitations prescribed in paragraph (b)(1) of this section is used as provided in paragraph (b)(2) of this section.

(1) *Limitations.* (i) It is used as a plasticizer in glassine and greaseproof paper.

(ii) The amount used does not exceed that required to accomplish its intended technical effect or exceed 15 percent by weight of the finished paper.

(2) *Conditions of use.* The glassine and greaseproof papers are used for packaging dry food or as the food-contact surface for dry food.

§ 176.350 Tamarind seed kernel powder.

Tamarind seed kernel powder may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Tamarind seed kernel powder is the ground kernel of tamarind seed (*Tamarindus indica* L.) after removal of the seed coat.

(b) It is used in the manufacture of paper and paperboard.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Subpart A [Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec.

- 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.
177.1020 Acrylonitrile/butadiene/styrene copolymer.
177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

21 CFR Ch. I (4–1–22 Edition)

- 177.1040 Acrylonitrile/styrene copolymer.
177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.
177.1060 *n*-Alkylglutarimide/acrylic copolymers.
177.1200 Cellophane.
177.1210 Closures with sealing gaskets for food containers.
177.1211 Cross-linked polyacrylate copolymers.
177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.
177.1310 Ethylene-acrylic acid copolymers.
177.1312 Ethylene-carbon monoxide copolymers.
177.1315 Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers.
177.1320 Ethylene-ethyl acrylate copolymers.
177.1330 Ionomeric resins.
177.1340 Ethylene-methyl acrylate copolymer resins.
177.1345 Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer.
177.1350 Ethylene-vinyl acetate copolymers.
177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.
177.1380 Fluorocarbon resins.
177.1390 Laminate structures for use at temperatures of 250 °F and above.
177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.
177.1400 Hydroxyethyl cellulose film, water-insoluble.
177.1420 Isobutylene polymers.
177.1430 Isobutylene-butene copolymers.
177.1440 4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.
177.1460 Melamine-formaldehyde resins in molded articles.
177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.
177.1500 Nylon resins.
177.1520 Olefin polymers.
177.1550 Perfluorocarbon resins.
177.1555 Polyarylate resins.
177.1556 Polyaryletherketone resins.
177.1560 Polyarylsulfone resins.
177.1570 Poly-1-butene resins and butene/ethylene copolymers.
177.1580 Polycarbonate resins.
177.1585 Polyester carbonate resins.
177.1590 Polyester elastomers.
177.1595 Polyetherimide resin.
177.1600 Polyethylene resins, carboxyl modified.
177.1610 Polyethylene, chlorinated.
177.1615 Polyethylene, fluorinated.
177.1620 Polyethylene, oxidized.
177.1630 Polyethylene phthalate polymers.
177.1632 Poly(phenyleneterephthalamide) resins.
177.1635 Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene).