

with food, subject to the provisions of this section.

(a) Ethylene polymer, chlorosulfonated is produced by chlorosulfonation of a carbon tetrachloride solution of polyethylene with chlorine and sulfuryl chloride.

(b) Ethylene polymer, chlorosulfonated shall meet the following specifications:

(1) Chlorine not to exceed 25 percent by weight.

(2) Sulfur not to exceed 1.15 percent by weight.

(3) Molecular weight is in the range of 95,000 to 125,000.

Methods for the specifications in this paragraph (b), titled "Chlorine and Bromine—Coulometric Titration Method by Aminco Chloridometer," "Hypolon® Synthetic Rubber—Determination of Sulfur by Parr Bomb," and ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," are incorporated by reference. Copies of the ASTM method may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103. Copies of the other two methods are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Copies of all three methods may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The additive is used as the article, or a component of articles, intended for use as liners and covers for reservoirs intended for the storage of water for drinking purposes.

(d) Substances permitted by § 177.2600 may be employed in the preparation of ethylene polymers, chlorosulfonated, subject to any limitations prescribed therein.

(e) The finished ethylene copolymers, chlorosulfonated shall conform to § 177.2600(e) and (g).

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

**§ 177.2250 Filters, microporous polymeric.**

Microporous polymeric filters identified in paragraph (a) of this section

may be safely used, subject to the provisions of this section, to remove particles of insoluble matter in producing, manufacturing, processing, and preparing bulk quantities of liquid food.

(a) Microporous polymeric filters consist of a suitably permeable, continuous, polymeric matrix of polyvinyl chloride, vinyl chloride-propylene, or vinyl chloride-vinyl acetate, in which finely divided silicon dioxide is embedded. Cyclohexanone may be used as a solvent in the production of the filters.

(b) Any substance employed in the production of microporous polymeric filters that is the subject of a regulation in parts 170 through 189 of this chapter must conform with any specification in such regulation.

(c) Cyclohexanone when used as a solvent in the production of the filters shall not exceed 0.35 percent by weight of the microporous polymeric filters.

(d) The microporous polymeric filters may be colored with colorants used in accordance with § 178.3297 of this chapter.

(e) The temperature of food being processed through the microporous polymeric filters shall not exceed 180 °F.

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180 °F for each square foot of filter, prior to the filter's first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991]

**§ 177.2260 Filters, resin-bonded.**

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials,

together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that 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 production of resin-bonded filters include the following, subject to any limitations provided:

#### LIST OF SUBSTANCES AND LIMITATIONS

##### (1) *Fibers:*

Cellulose pulp.  
Cotton.  
Nylon. (From nylon resins complying with the provisions of applicable regulations in subchapter B of this chapter.  
Polyethylene terephthalate complying in composition with the provisions of §177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.  
Rayon (viscose).

##### (2) *Substances employed in fiber finishing:*

BHT.  
Butyl (or isobutyl) palmitate or stearate.  
2,5-Di-*tert*-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.  
Dimethylpolysiloxane.  
4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.  
Fatty acid (C<sub>10</sub>-C<sub>18</sub>) diethanolamide condensates.  
Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:  
Aluminum.  
Ammonium.  
Calcium.  
Magnesium.  
Potassium.  
Sodium.  
Triethanolamine.

Fatty acid (C<sub>10</sub>-C<sub>18</sub>) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).

Methyl esters of fatty acids (C<sub>10</sub>-C<sub>18</sub>).  
Mineral oil.

Polybutene, hydrogenated; complying with the identity prescribed under §178.3740 (b) of this chapter.

Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.

Ricebran oil.

Titanium dioxide.

##### (3) *Resins:*

Acrylic polymers produced by polymerizing ethyl acrylate alone or with one or more of the monomers: Acrylic acid, acrylonitrile, *N*-methylolacrylamide, and styrene. The finished copolymers shall contain at least 70 weight percent of polymer units derived from ethyl acrylate, no more than 2 weight percent of total polymer units derived from acrylic acid, no more than 10 weight percent of total polymer units derived from acrylonitrile, no more than 2 weight percent of total polymer units derived from *N*-methylolacrylamide, and no more than 25 weight percent of total polymer units derived from styrene. For use only as provided in paragraph (m) of this section.

Melamine-formaldehyde.

Melamine-formaldehyde chemically modified with one or more of the amine catalysts identified in §175.300(b)(3)(xiii) of this chapter.

Melamine-formaldehyde chemically modified with methyl alcohol.

Melamine-formaldehyde chemically modified with urea; for use only as provided for in paragraphs (e), (f), (g), (h), and (i) of this section.

Phenol-formaldehyde resins.

Polyvinyl alcohol.

Polyvinyl alcohol with the copolymer of acrylic acid-allyl sucrose.

Polyvinyl alcohol with melamine formaldehyde.

Polyvinyl acetate with melamine formaldehyde.

*p*-Toluenesulfonamide-formaldehyde chemically modified with one or more of the amine catalysts identified in §175.300 (b)(3)(xiii) of this chapter.

##### (4) *Adjuvant substances:*

Dimethyl polysiloxane with methylcellulose and sorbic acid (as an antifoaming agent).  
Phosphoric acid.

(5) *Colorants:* Colorants used in accordance with §178.3297 of this chapter.

(e) Resin-bonded filters conforming with the specifications of paragraph (e)

(1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to distilled water at 100 °F for 2 hours, yields total extractives not to exceed 2.8 percent by weight of the filter.

(2) *Conditions of use*. It is used to filter milk or potable water at operating temperatures not to exceed 100 °F.

(f) Resin-bonded filters conforming with the specifications of paragraph (f) (1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to distilled water at 145 °F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use*. It is used to filter milk or potable water at operating temperatures not to exceed 145 °F.

(g) Resin-bonded filters conforming with the specifications of paragraph (g) (1) of this section are used as provided in paragraph (g)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.5 percent by weight of the filter.

(2) *Conditions of use*. It is used to filter edible oils.

(h) Resin-bonded filters conforming with the specifications of paragraph (h) (1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to distilled water at 212 °F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use*. It is used to filter milk, coffee, tea, and potable water at temperatures not to exceed 212 °F.

(i) Resin-bonded filters conforming with the specifications of paragraph (i) (1) of this section are used as provided in paragraph (i)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use*. It is used in commercial filtration of bulk quantities of

nonalcoholic, aqueous foods having a pH above 5.0.

(j) Resin-bonded filters conforming with the specifications of paragraph (j) (1) of this section are used as provided in paragraph (j)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to 5 percent (by weight) acetic acid for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use*. It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH of 5.0 or below.

(k) Resin-bonded filters conforming with the specifications of paragraph (k) (1) of this section are used as provided in paragraph (k)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to 8 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use*. It is used in commercial filtration of bulk quantities of alcoholic beverages containing not more than 8 percent alcohol.

(l) Resin-bonded filters conforming with the specifications of paragraph (l) (1) of this section are used as provided in paragraph (l)(2) of this section:

(1) *Total extractives*. The finished filter, when exposed to 50 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use*. It is used in commercial filtration of bulk quantities of alcoholic beverages containing more than 8 percent alcohol.

(m) Resin-bonded filters fabricated from acrylic polymers as provided in paragraph (d)(3) of this section together with other substances as provided in paragraph (d), (1), (2), and (4) of this section may be used as follows:

(1) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 100

§ 177.2280

21 CFR Ch. I (4-1-01 Edition)

°F, provided that the finished filter when exposed to distilled water at 100 °F for 2 hours yields total extractives not to exceed 1 percent by weight of the filter.

(2) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 145 °F, provided that the finished filter when exposed to distilled water at 145 °F for 2 hours yields total extractives not to exceed 1.2 percent by weight of the filter.

(n) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991]

**§ 177.2280 4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.**

4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The basic thermosetting epoxy resin is made by reacting 4,4'-isopropylidenediphenol with epichlorohydrin.

(b) The resin may contain one or more of the following optional substances provided the quantity used does not exceed that reasonably required to accomplish the intended effect:

Allyl glycidyl ether .....	As curing system additive.
Di- and tri-glycidyl ester mixture resulting from the reaction of epichlorohydrin with mixed dimers and trimers of unsaturated C <sub>18</sub> monobasic fatty acids derived from animal and vegetable fats and oils.	As modifier at levels not to exceed equal parts by weight of the 4,4'-isopropylidenediphenol-epichlorohydrin basic resin and limited to use in contact with alcoholic beverages containing not more than 8 percent of alcohol.
1,2-Epoxy-3-phenoxypropane	As curing system additive.
Glyoxal .....	Do.
4,4'-Isopropylidenediphenol ...	Do.
4,4'-Methylenedianiline .....	Do.
m-Phenylenediamine .....	Do.
Tetrahydrophthalic anhydride	Do.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly

cleansed prior to their first use in contact with food.

(d) The provisions of this section are not applicable to 4,4'-isopropylidenediphenol-epichlorohydrin resins listed in other sections of parts 174, 175, 176, 177, 178 and 179 of this chapter.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984]

**§ 177.2355 Mineral reinforced nylon resins.**

Mineral reinforced nylon resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with nonacidic food (pH above 5.0) and at use temperatures not exceeding 212 °F. in accordance with the following prescribed conditions:

(a) For the purpose of this section the mineral reinforced nylon resins consist of nylon 66, as identified in and complying with the specifications of §177.1500, reinforced with up to 40 weight percent of calcium silicate and up to 0.5 weight percent 3-(triethoxysilyl) propylamine (Chemical Abstracts Service Registry No. 000919302) based on the weight of the calcium silicate.

(b) The mineral reinforced nylon resins may contain up to 0.2 percent by weight of titanium dioxide as an optional adjuvant substance.

(c) The mineral reinforced nylon resins with or without the optional substance described in paragraph (b) of this section, and in the form of 1/8-inch molded test bars, when extracted with the solvents, i.e., distilled water and 50 percent (by volume) ethyl alcohol in distilled water, at reflux temperature for 24 hours using a volume-to-surface ratio of 2 milliliters of solvent per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 5.0 milligrams per square inch of food-contact surface tested for each solvent.

(2) The ash after ignition of the extractives described in paragraph (c)(1) of this section, not to exceed 0.5 milligram per square inch of food-contact surface tested.