

Food and Drug Administration, HHS

§ 175.350

List of substances	Limitations
<p>Glycerol triacetate. Triethyl citrate. (iii) Adjuvants (release agents, waxes, and dispersants): Acetone. Amides (unsubstituted) of fatty acids from vegetable or animal oils. <i>n</i>-Butyl acetate. <i>n</i>-Butyl alcohol. Candelilla wax. Carnauba wax. 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, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).. 1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7). Ethyl acetate. Fatty acids from vegetable or animal oils and their aluminum, ammonium, calcium, magnesium, and sodium salts. Hexane. Methyl ethyl ketone. <i>N,N</i>-Dioleylethylenediamine (CAS Reg. No. 110-31-6) ... Petroleum waxes conforming to specifications included in a regulation in subchapter B of this chapter. Polyvinyl alcohol, minimum viscosity of 4% aqueous solution at 20 °C of 4 centipoises and percent alcoholysis of 87-100. Sodium dioctyl sulfosuccinate. Sodium dodecylbenzenesulfonate. Sodium lauryl sulfate. Sorbitan and sorbitol esters of fatty acids from vegetable or animal oils. Spermaceti wax. Tetrahydrofuran. Toluene. (iv) Preservatives: Silver chloride-coated titanium dioxide</p>	<p>For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation. For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coating. For use only in ionomeric resins complying with § 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article. For use only as a dispersing agent at levels not to exceed 6% of total coating weight in coatings for polyolefin films provided the finished polyolefin films contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types V, VIII, and IX. For use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.</p>

(c) 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 conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.17(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface.

(d) Acrylonitrile copolymers identified in this section shall comply with

the provisions of §180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 43 FR 7206, Feb. 21, 1978; 45 FR 6541, Jan. 29, 1980; 47 FR 22512, May 25, 1982; 49 FR 36497, Sept. 18, 1984; 50 FR 47209, Nov. 15, 1985; 56 FR 49674, Oct. 1, 1991; 61 FR 14246, Apr. 1, 1996; 63 FR 71017, Dec. 23, 1998; 64 FR 2568, Jan. 15, 1999; 65 FR 6892, Feb. 11, 2000; 65 FR 37041, June 13, 2000]

§ 175.350 Vinyl acetate/crotonic acid copolymer.

A copolymer of vinyl acetate and crotonic acid may be safely used as a coating or as a component of a coating

§ 175.360

21 CFR Ch. I (4-1-07 Edition)

which is the food-contact surface of polyolefin films intended for packaging food, subject to the provisions of this section.

(a) The copolymer may contain added optional substances to impart desired properties.

(b) The quantity of any optional substance does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitations further provided.

(c) Any optional substance that is the subject of a regulation in parts 174, 175, 176, 177, 178, and §179.45 of this chapter conforms with any specifications in such regulation.

(d) Optional substances as provided in paragraph (a) of this section include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for uses with a copolymer of vinyl acetate and crotonic acid and used in accordance with such sanction or approval.

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

List of substances	Limitations
Silica. Japan wax.	

(e) Copolymer of vinyl acetate and crotonic acid used as a coating or as a component of a coating conforming with the specifications of paragraph (e)(1) of this section are used as provided in paragraph (e)(2) of this section.

(1) *Specifications.* (i) The chloroform-soluble portion of the water extractives of the coated film obtained with distilled water at 120 °F for 24 hours does not exceed 0.5 milligram per square inch of coated surface.

(ii) The chloroform-soluble portion of the *n*-heptane extractives of the coated film obtained with *n*-heptane at 70 °F for 30 minutes does not exceed 0.5 milligram per square inch of coated surface.

(2) *Conditions of use.* The copolymer of vinyl acetate and crotonic acid is used as a coating or as a component of a coating for polyolefin films for packaging bakery products and confectionery.

§ 175.360 Vinylidene chloride copolymer coatings for nylon film.

Vinylidene chloride copolymer coatings identified in this section and applied on nylon film may be safely used as food-contact surfaces, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from nylon resins complying with §177.1500 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylic acid, acrylonitrile, ethyl acrylate, methacrylic acid, methyl acrylate, methyl methacrylate (CAS Reg. No. 80-62-6; maximum use level 6 weight percent) and 2-sulfoethyl methacrylate (CAS Reg. No. 10595-80-9; maximum use level 1 weight percent). The finished copolymers contain at least 50 weight percent of polymer units derived from vinylidene chloride. The finished coating produced from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with methyl methacrylate and/or 2-sulfoethyl methacrylate, or with methyl methacrylate and/or 2-sulfoethyl methacrylate together with one or more of the other monomers from this section, is restricted to use at or below room temperature.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate.

(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 conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface when tested by the methods described in §176.170(d) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with