

weight of the pressure-sensitive adhesive.

(9) Butanedioic acid, sulfo-1,4-di-(C₉-C₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid sulfo-1, 4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]) as a surface active agent at a level not to exceed 3.0 percent by weight of the finished pressure-sensitive adhesive.

(b) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to raw fruit and raw vegetables.

(1) Substances listed in paragraphs (a)(1), (a)(2), (a)(3), (a)(5), (a)(6), (a)(7), (a)(8), and (a)(9) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section.

(2) Substances identified in this subparagraph and subject to the limitations provided:

- BHA.
- BHT.
- Butadiene-acrylonitrile copolymer.
- Butadiene-acrylonitrile-styrene copolymer.
- Butadiene-styrene copolymer.
- Butyl rubber.
- Butylated reaction product of *p*-cresol and dicyclopentadiene produced by reacting *p*-cresol and dicyclopentadiene in an approximate mole ratio of 1.5 to 1.0, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent, for use at levels not to exceed 1.0 percent by weight of the adhesive formulation.
- Chlorinated natural rubber.
- Isobutylene-styrene copolymer.
- Petrolatum.
- Polybutene-1.
- Polybutene, hydrogenated; complying with the identity prescribed under §178.3740(b) of this chapter.
- Polyisobutylene.
- cis*-1,4-Polyisoprene.
- Polystyrene.
- Propyl gallate.
- Rapeseed oil, vulcanized.
- Rosins and rosin derivatives as provided in §178.3870 of this chapter.
- Rubber hydrochloride.
- Rubber (natural latex solids or crepe, smoked or unsmoked).
- Terpene resins (α - and β -pinene), homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.
- Tetrasodium ethylenediaminetetraacetate.

Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).

(c) 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 42 FR 15674, Mar. 22, 1977; 48 FR 15617, Apr. 12, 1983; 63 FR 3464, Jan. 23, 1998; 63 FR 51528, Sept. 28, 1998; 64 FR 48291, Sept. 3, 1999]

Subpart C—Substances for Use as Components of Coatings

§ 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: *Provided, however,* That any substance named in this paragraph and covered by a specific regulation in subchapter B of this chapter must meet any specifications in such regulation.

List of substances	Limitations
Aluminum stearate. Ammonium lauryl sulfate. Borax	Not to exceed the amount required as a preservative in emulsion defoamer. Do.
Disodium hydrogen phosphate Formaldehyde. Glyceryl monostearate. Methyl cellulose. Mineral oil. Paraffin wax. Potassium hydroxide. Potassium persulfate. Tallow. Tetrasodium pyrophosphate. Titanium dioxide.	

§ 175.230

(c) The coating in the form in which it contacts food meets the following tests:

(1) An appropriate sample when exposed to distilled water at 212 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

(2) An appropriate sample when exposed to *n*-heptane at 120 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

§ 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides	Complying with 172.828 of this chapter.
Cellulose acetate butyrate. Cellulose acetate propionate. Mineral oil, white	For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with § 172.878 of this chapter.

§ 175.250 Paraffin (synthetic).

Synthetic paraffin may be safely used as an impregnant in, coating on, or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and may be further treated by percolation through activated charcoal. This mixture can be fractionated

21 CFR Ch. I (4–1–14 Edition)

into its components by a solvent separation method, using synthetic isoparaffinic petroleum hydrocarbons complying with § 178.3530 of this chapter.

(b) Synthetic paraffin shall conform to the following specifications:

(1) *Congealing point.* There is no specification for the congealing point of synthetic paraffin components, except those components that have a congealing point below 50 °C when used in contact with food Types III, IVA, V, VIIA, and IX identified in table 1 of § 176.170(c) of this chapter and under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter shall be limited to a concentration not exceeding 15 percent by weight of the finished coating. The congealing point shall be determined by ASTM method D938-71 (Reapproved 1981), “Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum,” 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.

(2) *Oil content.* The substance has an oil content not exceeding 2.5 percent as determined by ASTM method D721-56T, “Tentative Method of Test for Oil Content of Petroleum Waxes” (Revised 1956), which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

(3) *Absorptivity.* The substance has an absorptivity at 290 millimicrons in decahydronaphthalene at 88 °C not exceeding 0.01 as determined by ASTM method E131-81a, “Standard Definitions of Terms and Symbols Relating to Molecular-Spectroscopy,” which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The provisions of this section are not applicable to synthetic paraffin