

§ 172.180

21 CFR Ch. I (4–1–14 Edition)

storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 °F or below) until consumed.

(e) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

§ 172.180 Stannous chloride.

The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

§ 172.185 TBHQ.

The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948-33-0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 126.5 °C–128.5 °C.

(b) It is used as an antioxidant alone or in combination with BHA and/or BHT.

(c) The total antioxidant content of a food containing the additive will not

exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.190 THBP.

The food additive THBP (2,4,5-trihydroxybutyrophenone) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 149 °C–153 °C.

(b) It is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

Subpart C—Coatings, Films and Related Substances

§ 172.210 Coatings on fresh citrus fruit.

Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

(a) The coating is applied in the minimum amount required to accomplish the intended effect.

(b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.

(2) One or more of the following:

Component	Limitations
Fatty acids	Complying with § 172.860.
Oleic acid derived from tall oil fatty acids	Complying with § 172.862.
Partially hydrogenated rosin	Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100 °C. Color of WG or paler.
Pentaerythritol ester of maleic anhydride-modified wood rosin.	Acid number of 134–145; drop-softening point of 127 °C–173 °C; saponification number of less than 280; and a color of M or paler.
Do	Acid number of 176–186; drop-softening point of 110 °C–118 °C; saponification number of less than 280; and a color of M or paler.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyhydric alcohol diesters of oxidatively refined (Gersthofen process) montan wax acids.	Complying with § 178.3770 of this chapter and having a dropping point of 77 to 83 °C (170.6 to 181.4 °F), as determined by ASTM Method D566–76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference (Copies are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or 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), using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.
Sodium lauryl sulfate	Complying with § 172.822. As a film former.

Food and Drug Administration, HHS

§ 172.215

Component	Limitations
Wood rosin	Color of K or paler.

(3) In lieu of the components listed in paragraph (b) (2) and (4) of this section, the following copolymer and one or more of the listed adjuvants.

Component	Limitations
Vinyl chloride-vinylidene chloride copolymer	As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyvinylpyrrolidone	As an adjuvant.
Potassium persulfate	Do.
Propylene glycol alginate	Do.
Sodium decylbenzenesulfonate	Do.

(4) In lieu of the components listed in paragraph (b) (2) and (3) of this section, the following rosin derivative and either or both of the listed adjuvants:

Component	Limitations
Calcium salt of partially dimerized rosin	Having a maximum drop-softening point of 197 °C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95 °C to 105 °C and a color of WG or paler.
Petroleum naphtha	As adjuvant. Complying with § 172.250.
Sperm oil	As adjuvant.

[42 FR 14491, Mar. 15, 1977; 49 FR 5747, Feb. 15, 1984, as amended at 51 FR 2693, Jan. 21, 1986; 52 FR 18911, May 20, 1987; 61 FR 14245, Apr. 1, 1996]

§ 172.215 Coumarone-indene resin.

The food additive coumarone-indene resin may be safely used on grapefruit, lemons, limes, oranges, tangelos, and tangerines in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the polymerization of a crude, heavy coal-tar solvent naphtha meeting the following specifications:

(1) It is a mixture of indene, indan (hydrindene), substituted benzenes, and related compounds.

(2) It contains no more than 0.25 percent tar bases.

(3) 95 percent distills in the range 167 °C–184 °C.

(b) The food additive meets the following specifications:

(1) Softening point, ring and ball: 126 °C minimum 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.

(2) Refractive index ($n^{25/D}$) 1.63–1.64.

(c) It is used or intended for use as a protective coating for grapefruit, lemons, limes, oranges, tangelos, and tangerines whereby the maximum amount of the resin remaining on the fruit does not exceed 200 parts per million on a fresh-weight basis.

(d) To assure safe use of the additive:

(1) The label of the market package or any intermediate premix of the additive shall bear, in addition to the other information required by the act:

(i) The name of the additive, coumarone-indene resin.

(ii) A statement of the concentration of the additive therein.