

Food and Drug Administration, HHS

§ 178.3870

in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to any limitations provided therein:

List of substances	Limitations
Copolymer of isobutylene modified with isoprene. Petroleum wax, Type I and Type II. Polyethylene. Rosins and rosin derivatives as provided in § 178.3870. Synthetic wax polymer as described in § 176.170(a)(5) of this chapter.	Not to exceed 5 percent by weight of the petroleum wax.

(e) Reinforced wax conforming with the specifications in this paragraph is used as provided in paragraph (e)(2) of this section.

(1) The chloroform-soluble portion of the water extract obtained by exposing reinforced wax to demineralized water

at 70 °F for 48 hours shall not exceed 0.5 milligram per square inch of food-contact surface.

(2) It is used as a packaging material or component of packaging materials for cheese and cheese products.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 1288, Jan. 12, 1982]

§ 178.3860 Release agents.

Substances listed in paragraph (b) of this section may be safely used as release agents in petroleum wax complying with § 178.3710 and in polymeric resins that contact food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect or any limitations prescribed in this section.

(b) Release agents:

List of substances	Limitations
Erucamide (erucylamide). Formaldehyde, polymer with 1-naphthalenol (CAS Reg. No. 25359-91-5).	For use only as an antiscaling or release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers, provided that the residual levels of the additive in the polymer do not exceed 4 parts per million.
<i>N,N'</i> -Dioleylethylenediamine	For use only in polyvinyl chloride films in amounts such that the concentration of the substance in these films in the form in which the films contact food shall not exceed 0.055 milligram of the substance per square inch of film.
Oleyl palmitamide. Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b). Poly(vinyl acetate/vinyl <i>N</i> -octadecylcarbamate) (CAS Reg. No. 70892-21-6) produced by the reaction between stoichiometrically equivalent amounts of octadecyl isocyanate and vinyl alcohol/vinyl acetate copolymer; minimum average molecular weight is 500,000.	For use only subject to the limitations prescribed for hydrogenated polybutene under § 178.3740(b). For use only in application to the backing of pressuresensitive adhesive tapes at levels not to exceed 0.2 milligram per square centimeter (1.29 milligrams per square inch) of backing.
Rice bran wax	For use only in plastics intended for contact with dry foods identified as Type VIII in table 1 of § 176.170(c) of this chapter, at levels not in excess of 1.0 percent by weight of the polymer.
Saturated fatty acid amides manufactured from fatty acids derived from animal, marine, or vegetable fats and oils. Stearyl erucamide.	

[42 FR 14609, Mar. 15, 1977, as amended at 44 FR 69649, Dec. 4, 1979; 46 FR 51902, Oct. 23, 1981; 61 FR 25396, May 21, 1996; 61 FR 42381, Aug. 15, 1996]

§ 178.3870 Rosins and rosin derivatives.

The rosins and rosin derivatives identified in paragraph (a) of this section may safely be used in the manufacture of articles or 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 rosins and rosin derivatives are identified as follows:

- (1) Rosins:
 - (i) Gum rosin, refined to color grade of K or paler.
 - (ii) Wood rosin, refined to color grade of K or paler.

(iii) Tall oil rosin, refined to color grade of K or paler.

(iv) Dark tall oil rosin, a fraction resulting from the refining of tall oil rosin produced by multicolumnar distillation of crude tall oil to effect removal of fatty acids and pitch components and having a saponification number of from 110-135 and 32 percent-44 percent rosin acids.

(v) Dark wood rosin, all or part of the residue after the volatile terpene oils are distilled from the oleoresin extracted from pine wood.

(2) Modified rosins manufactured from rosins identified in paragraph (a)(1) of this section:

(i) Partially hydrogenated rosin, catalytically hydrogenated to a maximum refractive index of 1.5012 at 100 °C, and a color of WG or paler.

(ii) Fully hydrogenated rosin, catalytically hydrogenated to a maximum dehydroabietic acid content of 2 percent, a minimum drop-softening point of 79 °C, and a color of X or paler.

(iii) Partially dimerized rosin, dimerized by sulfuric acid catalyst to a drop-softening point of 95°-105 °C and a color of WG or paler.

(iv) Fully dimerized rosin, dimerized by sulfuric acid catalyst, and from which sufficient nondimerized rosin has been removed by distillation to achieve a minimum drop-softening point of 143 °C, and a color of H or paler.

(v) Disproportionated rosin, catalytically disproportionated to a minimum dehydroabietic acid content of 35 percent, a maximum abietic acid content of 1 percent, a maximum content of substituted phenanthrenes (as retene) of 0.25 percent, and a color of WG or paler.

(3) Rosin esters manufactured from rosins and modified rosins identified in paragraphs (a)(1) and (2) of this section:

(i) Glycerol ester of wood rosin purified by steam stripping to have an acid number of 3 to 9, a drop-softening point of 88°-96 °C, and a color of N or paler.

(ii) Glycerol ester of partially hydrogenated wood rosin, having an acid number of 3 to 10, a drop-softening point of 79°-88 °C, and a color of N or paler.

(iii) Glycerol ester of partially dimerized rosin, having an acid number

of 3 to 8, a drop-softening point of 109°-119 °C, and a color of M or paler.

(iv) Glycerol ester of fully dimerized rosin, having an acid number of 5 to 16, a drop-softening point of 165°-175 °C, and a color of H or paler.

(v) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 138°-146 °C, a color of M or paler, and a saponification number less than 280.

(vi) Methyl ester of rosin, partially hydrogenated, purified by steam stripping to have an acid number of 4 to 8, a refractive index of 1.5170 to 1.5205 at 20 °C, and a viscosity of 23 to 66 poises at 25 °C.

(vii) Pentaerythritol ester of wood rosin, having an acid number of 6 to 16, a drop-softening point of 109°-116 °C, and a color of M or paler.

(viii) Pentaerythritol ester of partially hydrogenated wood rosin, having an acid number of 7 to 18, a drop-softening point of 102°-110 °C, and a color of K or paler.

(ix) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 8 to 16, a drop-softening point of 154°-162 °C, a color of M or paler, and having a saponification number less than 280.

(x) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 9 to 16, a drop-softening point of 130°-140 °C, a color of N or paler, and having a saponification number less than 280.

(xi) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 134 to 145, a drop-softening point of 127°-137 °C, a color of M or paler, and having a saponification number less than 280.

(xii) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 131°-137 °C, a color of N or paler, and having a saponification number less than 280.

(xiii) Pentaerythritol ester of maleic anhydride-modified wood rosin, further modified by reaction with 4,4'-isopropyl-idenediphenol-formaldehyde condensate, having an acid number of 10 to 22, a drop-softening point of 162°-172 °C, a color of K or paler, a saponification number less than 280, and a

maximum ultraviolet absorbance of 0.14 at 296 m μ (using a 1-centimeter cell and 200 milligrams of the rosin ester per liter of solvent consisting of ethyl alcohol made alkaline by addition of 0.1 percent of potassium hydroxide).

(xiv) Mixed methyl and pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 73 to 83, a drop-softening point of 113°–123 °C, a color of M or paler, and a saponification number less than 280.

(xv) Triethylene glycol ester of partially hydrogenated wood rosin, having an acid number of 2 to 10, a color of K or paler, and a viscosity of 350 to 425 seconds Saybolt at 100 °C.

(xvi) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 17 to 23, a drop-softening point of 136°–140 °C, a color of M or paler, and a saponification number less than 280. For use only in cellophane complying with §177.1200 of this chapter.

(xvii) Citric acid-modified glycerol ester of rosin, having an acid number less than 20, a drop-softening point of 105°–115 °C, and a color of K or paler. For use only as a blending agent in coatings for cellophane complying with §177.1200 of this chapter.

(xviii) Glycerol ester of tall oil rosin, purified by steam stripping to have an acid number of 5–12, a softening point of 80°–88 °C, and a color of N or paler.

(xix) Glycerol ester of maleic anhydride-modified tall oil rosin, having an acid number of 30 to 40, a drop-softening point of 141°–146 °C, a color of N or paler, and a saponification number less than 280.

(xx) Glycerol ester of disproportionated tall oil rosin, having an acid number of 5 to 10, a drop-softening point of 84°–93 °C, a color of WG or paler, and a saponification number less than 180.

(4) Rosin salts and sizes—Ammonium, calcium, potassium, sodium, or zinc salts of rosin manufactured by the partial or complete saponification of any one of the rosins or modified rosins identified in paragraph (a)(1) and (2) of this section, or blends thereof, and with or without modification by reaction with one or more of the following:

- (i) Formaldehyde.
- (ii) Fumaric acid.

(iii) Maleic anhydride.

(iv) Saligenin.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(c) The use in any substance or article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter shall conform with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(d) The provisions of this section are not applicable to rosins and rosin derivatives identified in §175.300(b)(3)(v) of this chapter and used in resinous and polymeric coatings complying with §175.300 of this chapter.

(e) The provisions of this section are not applicable to rosins and rosin derivatives identified in §175.105(c)(5) of this chapter and used in defoaming agents complying with §176.210 of this chapter, food-packaging adhesives complying with §175.105 of this chapter, and rubber articles complying with §177.2600 of this chapter.

(f) The analytical methods for determining whether rosins and rosin derivatives conform to the specifications prescribed in paragraph (a) of this section are as follows:

(1) Color: Color shall be as determined by ASTM method D509–70 (Reapproved 1981), “Standard Methods of Sampling and Grading Rosin,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) Refractive index: Refractive index shall be as determined by ASTM method D1747–62 (Reapproved 1978), “Standard Test Method for Refractive Index of Viscous Materials,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(3) Acid number: Acid number shall be as determined by ASTM method D465–82, “Standard Test Methods for Acid Number of Rosin,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

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(4) Viscosity: Viscosity in poises shall be as determined by ASTM method D1824-66 (Reapproved 1980), "Standard Test Method for Apparent Viscosity of Plastics and Organosols at Low Shear Rates by Brookfield Viscometer," and in Saybolt seconds by ASTM method D88-81, "Standard Test Method for Saybolt Viscosity," which are incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(5) Softening point: Softening point shall be as determined by ASTM method E28-67, "Standard Test Method for Softening Point by Ring and Ball Apparatus" (Reapproved 1977), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(6) Analytical methods for determining drop-softening point, saponification number, and any other specifications not listed under paragraphs (f)(1) through (5) of this section, titled: (i) "Determination of Abeitic Acid and Dehydroabietic Acid in Rosins"; (ii) "Determination of Softening Point of Solid Resins"; (iii) "Determination of Saponification Number of Rosin Esters," and (iv) "Determination of Phenolic Modification of Rosin Derivatives," which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for in-

spection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11849, Mar. 19, 1982; 49 FR 10113, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 178.3900 Sodium pentachlorophenate.

Sodium pentachlorophenate may be safely used as a preservative for ammonium alginate employed as a processing aid in the manufacture of polyvinyl chloride emulsion polymers intended for use as articles or components of articles that contact food at temperatures not to exceed room temperature. The quantity of sodium pentachlorophenate used shall not exceed 0.5 percent by weight of ammonium alginate solids.

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

The substances listed in this section may be safely used in surface lubricants employed in the manufacture of metallic articles that contact food, subject to the provisions of this section.

(a) The following substances may be used in surface lubricants used in the rolling of metallic foil or sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of metallic food-contact surface:

(1) Substances identified in paragraphs (b)(1) and (2) of this section.

(2) Substances identified in this paragraph.

List of substances	Limitations
<p>α-Butyl-Ω-hydroxypoly (oxyethylene)-poly (oxypropylene) (CAS Reg. No. 9038-95-3) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol and having a minimum molecular weight of 1,000.</p>	
<p>α-Butyl-Ω-hydroxypoly(oxypropylene) (CAS Reg. No. 9003-13-8) having a minimum molecular weight of 1000.</p>	
<p>α-Lauroyl-Ω-hydroxypoly(oxyethylene) (CAS Reg. No. 9004-81-3) having a minimum molecular weight of 200.</p>	
<p>Acetate esters derived from synthetic straight chain alcohols (complying with §172.864 of this chapter) that have even numbers of carbon atoms in the range C₈-C₁₈.</p>	
<p><i>alpha</i>-Alkyl-<i>omega</i>-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of C₁₂-C₁₅ straight chain primary alcohols with an average of 3 moles of ethylene oxide (CAS Reg. No. 6002-97-1).</p>	
<p>Benzotriazole (CAS Reg. No. 95-14-7)</p>	