Ultra-filtration membranes may be safely used in the processing of food, under the following prescribed conditions:

(a)(1) Ultra-filtration membranes that consist of paper impregnated with cured phenol-formaldehyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(a)(2) Ultra-filtration membranes that consist of a sintered carbon support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 12 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(a)(3) Ultra-filtration membranes that consist of an aluminum oxide support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 5 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(a)(4) Ultrafiltration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloidally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(e) Ultrafiltration membranes identified in paragraph (a)(4) may be used to filter aqueous or acidic foods containing up to 13 percent of alcohol at temperatures not to exceed 21 °C (70 °F).

(f) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

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

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart A [Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

Sec.

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178.3290 Chromic chloride complexes.
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178.3500 Glycerin, synthetic.
178.3505 Glycerol tri-(12-acetoxystearate).
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178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.
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178.3600 Methyl glycoside-coconut oil ester.
178.3630 a-Methylstyrene-vinyltoluene resins, hydrogenated.
178.3650 Mineral oil.
178.3650 Odorless light petroleum hydrocarbons.
§ 178.1005 Hydrogen peroxide solution.

Hydrogen peroxide solution identified in this section may be safely used to sterilize polymeric food-contact surfaces identified in paragraph (e)(1) of this section.

(a) Identity. For the purpose of this section, hydrogen peroxide solution is an aqueous solution containing not more than 35 percent hydrogen peroxide (CAS Reg. No. 7722-84-1) by weight, meeting the specifications prescribed in paragraph (c) of this section.

(b) Optional adjuvant substances. Hydrogen peroxide solution identified in paragraph (a) of this section may contain substances generally recognized as safe in or on food, substances generally recognized for their intended use in food packaging, substances used in accordance with a prior sanction or approval, and substances permitted by applicable regulations in parts 174 through 179 of this chapter.

(c) Specifications. Hydrogen peroxide solution shall meet the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), pp. 146-147, which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), and the United States Pharmacopeia XX (1980), except that hydrogen peroxide may exceed the concentration specified therein.

(d) Limitations. No use of hydrogen peroxide solution in the sterilization of food packaging material shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in distilled water packaged under production conditions (assay to be performed immediately after packaging).

(e) Conditions of use. (1) Hydrogen peroxide solution identified in and complying with the specifications in this section may be used by itself or in combination with other processes to treat food-contact surfaces to attain commercial sterility at least equivalent to that attainable by thermal processing for metal containers as provided for in part 113 of this chapter. Food-contact surfaces include the following:

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Food and Drug Administration, HHS

§ 178.1010 Sanitizing solutions.

Sanitizing solutions may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.

(1) An aqueous solution containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium.

(2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium, or calcium.

(3) An aqueous solution containing potassium iodide, sodium p-toluenesulfonchloroamide, and sodium lauryl sulfate.

(4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90–100 °C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.

(5) An aqueous solution containing elemental iodine, hydriodic acid, a-(p-nonylphenyl)-omega-hydroxypoly-(oxyethylene) (complying with the identity prescribed in §178.3400(c) and having a maximum average molecular weight of 748) and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(6) An aqueous solution containing elemental iodine, sodium iodide, sodium diocetyl-sulfosuccinate, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900).

(7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a minimum average molecular weight of 2,400 and α-lauroyl-omega-hydroxy poly(oxyethylene) with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. In addition to use on food-processing equipment and utensils, this solution may be used on beverage containers, including milk containers or equipment. Rinse water treated with this solution can be recirculated as a preliminary rinse. It is not to be used as final rinse.

(9) An aqueous solution containing n-alkyl (C12-C18) benzyl(dimethylammonium chloride compounds having
average molecular weights of 351 to 380. The alkyl groups consist principally of groups with 12 to 16 carbon atoms and contain not more than 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain either ethyl alcohol or isopropyl alcohol as an optional ingredient.

10. An aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecylbenzenesulfonic acid. In addition to use on food-processing equipment and utensils and other food-contact articles, this solution may be used on beverage containers except milk containers or equipment.

11. An aqueous solution containing equal amounts of n-alkyl (C_{12}-C_{18}) benzyl dimethyl ammonium chloride and n-alkyl (C_{12}-C_{14}) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

12. An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000). (15) An aqueous solution containing lithium hypochlorite.

16. An aqueous solution containing equal amounts of n-alkyl (C_{12}-C_{18}) benzyl dimethyl ammonium chloride and n-alkyl (C_{12}-C_{14}) dimethyl ethylbenzyl ammonium chloride (having average molecular weights of 377 to 384), with the optional adjuvant substances tetrasodium ethylenediaminetetraacetate and/or alpha-(p-nonylphenol)-omega-hydroxy poly (oxyethylene), having an average poly-(oxyethylene) content of 11 moles. Alpha-hydro-omega-hydroxypoly- (oxyethylene) poly(oxypropylene) (15 to 18 mole minimum) poly (oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9003-11-6) may be used in lieu of alpha- (p-nonylphenol)-omega-hydroxy-poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

17. An aqueous solution containing di-n-alkyl(C_{8}-C_{10})dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethyl alcohol or isopropyl alcohol. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

18. An aqueous solution containing n-alkyl(C_{12}-C_{18}) benzyl dimethylammonium chloride, sodium metaborate, alpha-terpineol and alpha-[p-(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy-poly (oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide.

19. An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

20. An aqueous solution containing ortho-phenylphenol, ortho-benzyl-para-chlorophenol, para-tertiaryamylphenol, sodium-alpha-alkyl(C_{12}-C_{18})-omega-hydroxypoly (oxyethylene) sulfate with the
poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21) An aqueous solution containing sodium dodecylbenzenesulfonate in addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(22) An aqueous solution containing n-alkyl \((C_{12}-C_{18})\) benzyl dimethylammonium chloride compounds having average molecular weights of 332-361. (2) n-alkyl \((C_{12}-C_{18})\) benzyl dimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without more than 1 percent of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

(23) An aqueous solution containing \(\text{oxypropylene)}\) poly(oxyethylene)) dimethylammonium chloride and didecyldimethylammonium chloride.

(24) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), alpha-(p-(1,1,3,3-tetramethylbutyl)-phenyl)-omega-hydroxy poly(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and alpha-alkyl\((C_{12}-C_{18})\)-omega-hydroxy poly(oxyethylene) poly(oxypropylene) (having an average molecular weight of 965).

(25) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), potassium iodide (CAS Reg. No. 7681-11-0), and isopropanol (CAS Reg. No. 67-63-0). In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.

(26) [Reserved]

(27) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), and sodium 1-octanesulfonate (CAS Reg. No. 5324-84-5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No. 67-63-0) as an optional ingredient.

(28) An aqueous solution containing sulfonated 9-octadecenoic acid (CAS Reg. No. 69988-76-1) and sodium xylene sulfonate (CAS Reg. No. 1300-72-7).

(29) An aqueous solution containing dodecyl diphenyloxidesulfonic acid (CAS Reg. No. 30260-73-2), sulfonated tall oil fatty acid (CAS Reg. No. 68309-27-3), and neo-decanoic acid (CAS Reg. No. 26896-20-8). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(30) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).

(31) An aqueous solution containing elemental iodine, alpha-alkyl\((C_{10}-C_{14})\)-omega-hydroxy poly(oxyethylene) poly(oxypropylene) of average molecular weight between 768 and 837, and alpha-alkyl\((C_{12}-C_{18})\)-omega-hydroxy poly(oxyethylene) poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(32) An aqueous solution containing (i) di-n-alkyl\((C_{6}-C_{10})\) dimethylammonium chloride compounds having average molecular weights of 332 to 361, (ii) n-alkyl\((C_{12}-C_{18})\) benzyl dimethylammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) alpha-(p-nonylphenyl)-omega-hydroxy poly(oxyethylene) produced by the condensation of 1 mole of p-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(33) An aqueous solution containing (i) di-n-alkyl\((C_{6}-C_{10})\)-dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) n-alkyl\((C_{12}-C_{18})\) benzyl dimethylammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16...
carbon atoms with no more than 1 percent of the groups with 8 to 10; and (iii) tetradsodium ethylenediamine tetraacetate. Additionally, the aqueous solution contains either alpha-(p-nonylphenyl)-omega-hydroxy(poly(oxyethylene) or alpha-alkyl(C_{11}-C_{15})-omega-hydroxy(poly(oxyethylene), each produced with 9 to 13 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(34) An aqueous solution of an equilibrium mixture of oxychloro species (predominantly chlorite, chlorate, and chlorine dioxide) generated either (i) by directly metering a concentrated chlorine dioxide solution, prepared just prior to use, into potable water to provide the concentration of available chlorine dioxide stated in paragraph (c)(29) of this section, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominantly chlorite and chlorate) followed by dilution with potable water to provide the concentration of available chlorine dioxide described in paragraph (c)(29) of this section.

(35) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), lactic acid (CAS Reg. No. 50-21-5), phosphoric acid (CAS Reg. No. 7664-39-2) and a mixture of the sodium salt of naphthalenesulfonic acid (CAS Reg. No. 1321-69-3); the methyl, dimethyl, and trimethyl derivatives of the sodium salt of naphthalenesulfonic acid; and a mixture of the sodium salt of naphthalenesulfonic acid, and the methyl, dimethyl, and trimethyl derivatives of the sodium salt of naphthalenesulfonic acid alkylated at 3 percent by weight with C_{6}-C_{9} linear olefins, as components of a sanitizing solution to be used on food-processing equipment and utensils. The methyl and dimethyl substituted derivatives (described within this paragraph (b)(35)) constitute no less than 70 percent by weight of the mixture of naphthalenesulfonates.

(36) The sanitizing solution contains decanoic acid (CAS Reg. No. 334-48-5); octanoic acid (CAS Reg. No. 124-07-2); lactic acid (CAS Reg. No. 50-21-5); phosphoric acid (CAS Reg. No. 7664-39-2); a mixture of 1-octanesulfonic-2-sulfinic acid (CAS Reg. No. 113652-56-5); and the optional ingredient FD&C Yellow No. 5 (CAS Reg. No. 001934210). In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(37) The sanitizing solution contains sodium hypochlorite (CAS Reg. No. 7681-52-9), trisodium phosphate (CAS Reg. No. 7601-54-9), sodium lauryl sulfate (CAS Reg. No. 151-21-3), and potassium permanganate (CAS Reg. No. 7722-64-7); Magnesium oxide (CAS Reg. No. 1309-48-4) and potassium bromide (CAS Reg. No. 7758-02-3) may be added as optional ingredients to this sanitizing solution. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(38) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1); peroxyacetic acid (CAS Reg. No. 79-21-0); acetic acid (CAS Reg. No. 64-19-7); sulfuric acid (CAS Reg. No. 7664-93-9); and 2,6-pyridinedicarboxylic acid (CAS Reg. No. 499-83-2). In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(39) An aqueous solution containing phosphoric acid (CAS Reg. No. 7664-38-2); octenyl succinic acid (CAS Reg. No. 28805-58-5); N,N-dimethyloctanamine (CAS Reg. No. 7378-99-6); and a mixture of n-carboxylic acids (C_{6}-C_{12}, consisting of not less than 56 percent octanoic acid and not less than 40 percent decanoic acid). This solution may be used on food-processing equipment and utensils, including dairy-processing equipment.

(40) An aqueous solution prepared by combining elemental iodine (CAS Reg. No. 7553-56-2); hydriodic acid (CAS Reg. No. 10034-85-2); sodium N-cyclohexyl-N-palmitoyl taurate (CAS Reg. No. 132-43-4); chloroacetic acid, sodium salt reaction products with 4,5-dihydro-
undecyl-1H-imidazole-1-ethanol and sodium hydroxide (CAS Reg. No. 68608-66-2); dodecylbenzene sulfonic acid (CAS Reg. No. 27176-87-0); phosphoric acid (CAS Reg. No. 7664-38-2); isopropyl alcohol (CAS Reg. No. 67-63-0); and calcium chloride (CAS Reg. No. 10043-52-4). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places, subject to the limitations in paragraph (c)(39) of this section.

(43) An aqueous solution of iodine and hypochlorous acid generated by the dilution of an aqueous acidic (21.5 percent nitric acid) solution of iodine monochloride. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(44) An aqueous solution of citric acid, disodium ethylenediaminetetraacetate, sodium lauryl sulfate, and monosodium phosphate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(45) An aqueous solution of hydrogen peroxide, acetic acid, peroxycetic acid, octanoic acid, peroxoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places, subject to the limitations in paragraph (c)(39) of this section.

(c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:

(1) Solutions identified in paragraph (b)(1) of this section will provide not more than 200 parts per million of available halogen determined as available chlorine.

(2) Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine.

(3) Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium p-toluenesulfonylchloramide and sodium lauryl sulfate at a level not in excess of the minimum required to produce their intended functional effect.

(4) Solutions identified in paragraph (b)(4), (5), (6), (8), (13), and (14) of this section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of...
polyoxyethylene-polyoxypropylene
block polymers (having a minimum av-
erage molecular weight of 2,800) or not
more than 40 parts per million of iso-
propyl alcohol.

(6) Solutions identified in paragraph
(b)(9) of this section shall provide when
ready to use no more than 200 parts per
million of the active quaternary com-
 pound.

(7) Solutions identified in paragraph
(b)(10) of this section shall provide not
more than sufficient trichloromelamine to produce 200 parts per
million of available chlorine and ei-
ther sodium lauryl sulfate at a level
not in excess of the minimum required to produce its intended functional ef-
fect or not more than 400 parts per mil-
 lion of dodecylbenzenesulfonic acid.

(8) Solutions identified in paragraph
(b)(11) of this section shall provide, when ready to use, not more than 200 parts per million of active quaternary com-
 pound.

(9) The solution identified in para-
graph (b)(12) of this section shall pro-
vide not more than 200 parts per mil-
 lion of sulfonated oleic acid, sodium
salt.

(10) Solutions identified in paragraph
(b)(15) of this section will provide not
more than 200 parts per million of av-
ailable chlorine and not more than 30
ppm lithium.

(11) Solutions identified in paragraph
(b)(16) of this section shall provide not
more than 200 parts per million of ac-
tive quaternary compound.

(12) Solutions identified in paragraph
(b)(17) of this section shall provide, when ready to use, a level of 150 parts per
million of the active quaternary com-
 pound.

(13) Solutions identified in paragraph
(b)(18) of this section shall provide not
more than 200 parts per million of ac-
tive quaternary compound and not
more than 66 parts per million of alpha-[1,1,3,3-tetramethylbutyl]
phenyl]omega-hydroxypoly (oxy-
ethylene).

(14) Solutions identified in paragraph
(b)(19) of this section shall provide, when ready to use, a level of 100 parts per
million of available chlorine.

(15) Solutions identified in paragraph
(b)(20) of this section are for single use
applications only and shall provide,
when ready to use, a level of 800 parts
per million of total active phenols con-
sisting of 400 parts per million ortho-
phenylphenol, 320 parts per million
ortho-benzyl-para-chlorophenol and 80
parts per million para-
tertiaryamylphenol.

(16) Solution identified in paragraph
(b)(21) of this section shall provide not
more than 430 parts per million and not
less than 25 parts per million of sodium
dodecylbenzenesulfonate.

(17) Solutions identified in paragraph
(b)(22) of this section shall provide, when ready to use, at least 150 parts per
million and not more than 400 parts per
million of active quaternary com-
 pound.

(18) Solutions identified in paragraph
(b)(23) of this section shall provide at
least 150 parts per million and not
more than 200 parts per million of the
active quaternary compound.

(19) Solutions identified in parara-
graphs (b)(24), (b)(25), and (b)(43) of this
section shall provide at least 12.5 parts per
million and not more than 25 parts per
million of titratable iodine. The ad-
juvants used with the iodine shall not
be in excess of the minimum amounts
required to accomplish the intended
technical effect.

(20)–(22) [Reserved]

(22) Solutions identified in paragraph
(b)(27) of this section shall provide, when ready to use, at least 109 parts per
million and not more than 218 parts per
million of total active fatty acids
and at least 156 parts per million and
not more than 312 parts per million of
the sodium 1-octanesulfonate.

(23) Solutions identified in paragraph
(b)(28) of this section shall provide, when ready to use, at least 156 parts per
million and not more than 312 parts per
million of sulfonated 9-
octadecenoic acid, at least 31 parts per
million and not more then 62 parts per
million of sodium xylenesulfonate.

(24) Solutions identified in paragraph
(b)(29) of this section will provide at
least 237 parts per million and not
more than 474 parts per million
dodecyldiphenyloxidedisulfonic acid, at
least 33 parts per million and not more then 62 parts per
million of sodium xylenesulfonate.

(25) Solutions identified in paragraph
(b)(30) of this section will provide at
least 237 parts per million and not
more than 474 parts per million
dodecyldiphenyloxidedisulfonic acid, at
least 33 parts per million and not more than 174 parts per
million neo-decanoic acid.
(25) Solutions identified in paragraph (b)(30) of this section shall provide, when ready to use, not less than 550 parts per million and not more than 1,100 parts per million hydrogen peroxide, not less than 100 parts per million and not more than 200 parts per million peracetic acid, not less than 150 parts per million and not more than 300 parts per million acetic acid, and not less than 15 parts per million and not more than 50 parts per million 1-hydroxyethylidene-1,1-diphosphonic acid.

(26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(27) Solutions identified in paragraph (b)(32) of this section shall provide, when ready to use, at least 150 parts per million and no more than 400 parts per million of active quarternary compounds in solutions containing no more than 600 parts per million water hardness. The adjuvants used with the quarternary compounds will not exceed the amounts required to accomplish the intended technical effect.

(28) Solutions identified in paragraph (b)(33) of this section shall provide, when ready to use, at least 150 parts per million and not more than 600 parts per million of active quarternary compounds. The adjuvants used with the quarternary compounds shall not exceed the amounts required to accomplish the intended technical effect. Tetrasodium ethylenediamine tetraacetate shall be added at a minimum level of 60 parts per million. Use of these sanitizing solutions shall be limited to conditions of water hardness not in excess of 300 parts per million.

(29) Solutions identified in paragraph (b)(34) of this section should provide, when ready to use, at least 100 parts per million and not more than 200 parts per million available chlorine dioxide as determined by the method titled "Iodometric Method for the Determination of Available Chlorine Dioxide (50±250 ppm available ClO₂)", which is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(30) Solutions identified in paragraph (b)(35) of this section shall provide, when ready for use, at least 117 parts per million and not more than 234 parts per million of total fatty acids and at least 166 parts per million and not more than 332 parts per million of a mixture of naphthalenesulfonates. The adjuvants phosphoric acid and lactic acid, used with decanoic acid, octanoic acid, and sodium naphthalenesulfonate and its alkylated derivatives, will not be in excess of the minimum amounts required to accomplish the intended technical effects.

(31) Solutions identified in paragraph (b)(36) of this section shall provide, when ready for use, at least 29 parts per million and not more than 58 parts per million decanoic acid; at least 88 parts per million and not more than 176 parts per million of octanoic acid; at least 69 parts per million and not more than 138 parts per million of lactic acid; at least 256 parts per million and not more than 512 parts per million of phosphoric acid; at least 86 parts per million and not more than 172 parts per million of 1-octanesulfonic acid; at least 51 parts per million and not more than 102 parts per million of 1-octanesulfonic-2-sulfinic acid or 1,2-octanedisulfonic acid; and at least 10 parts per million of the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine. The colorant adjuvant FD&C Yellow No. 5 shall not be used in excess of the minimum amount required to accomplish the intended technical effect.

(32) The solutions identified in paragraph (b)(37) of this section without potassium bromide shall provide, when ready to use, at least 100 parts per million halogen determined as available chlorine; at least 2,958 parts per million and not more
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than 5,916 parts per million of tri-
sodium phosphate; at least 1 part per 
million and not more than 3 parts per 
million of sodium lauryl sulfate; and at 
least 0.3 part per million and not more 
0.7 part per million on potassium 
permanganate.

(ii) The solution identified in para-
graph (b)(37) of this section with potas-
sium bromide shall provide, when 
ready to use, at least 25 parts per mil-
lion and not more than 200 parts per 
million of available halogen deter-
dined as available chlorine; at least 15 
parts per million and not more than 46 
parts per million of potassium bro-
mide; at least 690 parts per million and 
not more than 2,072 parts per million of 
trisodium phosphate; at least 0.3 part 
per million and not more than 1 part 
per million of sodium lauryl sulfate; 
and at least 0.3 part per million and 
not more than 0.7 part per million of 

trium.
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octanesulfonate to 3.2 parts sulfuric acid.

(38) The solution identified in paragraph (b)(44) of this section shall pro-
vide, when ready for use, at least 16,450 parts per million and not more than 32,900 parts per million of citric acid; at least 700 parts per million and not more than 1,400 parts per million of disodium ethylenediaminetetraacetate; at least 175 parts per million and not more than 350 parts per million of sodium lauryl sulfate; and at least 175 parts per million and not more than 350 parts per million of monosodium phosphate.

(39)(i) The solution identified in paragraph (b)(45) of this section, when used on food processing equipment and utensils, including dairy and beverage-processing equipment but excluding food-contact surfaces in public eating places and dairy and beverage containers, shall provide when ready for use at least 72 parts per million and not more than 216 parts per million of hydrogen peroxide; at least 46 parts per million and not more than 138 parts per million of peroxycetic acid; at least 40 parts per million and not more than 122 parts per million of octanoic acid (including peroxyoctanoic acid); at least 281 parts per million and not more than 686 parts per million of acetic acid; at least 7 parts per million and not more than 34 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 36 parts per million and not more than 108 parts per million of sodium 1-octanesulfonate.

(ii) The solution identified in paragraph (b)(45) of this section, when used on food-contact equipment and utensils in warewashing machines, including warewashing machines in public eating places at temperatures no less than 120 °F (49 °C) shall provide when ready for use at least 30 parts per million and not more than 91 parts per million of hydrogen peroxide; at least 19 parts per million and not more than 58 parts per million of peroxycetic acid; at least 17 parts per million and not more than 52 parts per million of octanoic acid (including peroxyoctanoic acid); at least 119 parts per million and not more than 290 parts per million of acetic acid; at least 3 parts per million and not more than 14 parts per million of 1-
hydroxyethylidene-1,1-diphosphonic acid; and at least 15 parts per million and not more than 46 parts per million of sodium 1-octanesulfonate.

(iii) The solution identified in paragraph (b)(45) of this section, when used on dairy or beverage containers, shall provide when ready for use at least 36 parts per million and not more than 108 parts per million of hydrogen peroxide; at least 23 parts per million and not more than 69 parts per million of peroxycetic acid; at least 20 parts per million and not more than 61 parts per million of octanoic acid (including peroxyoctanoic acid); at least 140 parts per million and not more than 343 parts per million of acetic acid; at least 3 parts per million and not more than 17 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 18 parts per million and not more than 55 parts per million of sodium 1-octanesulfonate.

(40) The solution identified in paragraph (b)(46) of this section shall pro-
vide, when ready for use, at least 100 parts per million and not more than 200 parts per million of chlorine dioxide as determined by the method developed by Bio-cide International, Inc., entitled, "Iodometric Method for the Determination of Available Chlorine Dioxide (50±250 ppm Available ClO₂)", dated June 11, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this method are available from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC, at least 380 parts per million and not more than 760 parts per million of sodium gluconate; and at least 960 parts per million and not more than 1,920 parts per million of sodium mono-
didodecylphenoxybenzenedisulfonate.

Other components listed under paragraph (b)(46) of this section shall be
used in the minimum amount necessary to produce the intended effect.

(d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

[42 FR 14609, Mar. 16, 1977]

EDITORIAL NOTE: For Federal Register citations affecting §178.1010, see the List of CFR Sections Affected in the Finding Aids section of this volume.

Subpart C—Antioxidants and Stabilizers

§ 178.2010 Antioxidants and/or stabilizers for polymers.

The substances listed in paragraph (b) of this section may be safely used as antioxidants and/or stabilizers in polymers 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 quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-n-Alkyl-N′-(carboxymethyl)-N,N′-trimethylene diglycine; the alkyl group is even numbered in the range C14–C18 and the nitrogen content is in the range 5.4–5.6 weight percent.</td>
<td></td>
</tr>
<tr>
<td>Alkylthiophenolics: acid-catalyzed condensation reaction products of 4-nonylphenol, formaldehyde, and 1-dodecanethiol (CAS Reg. No. 164907–73–7).</td>
<td>For use only: 1. As component of nonfood articles complying with §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acyronitrile, butadiene-acyronitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with §177.1210 of this chapter or in coatings complying with §§175.300, §176.170, or §175.320 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch.</td>
</tr>
<tr>
<td>p-tert-Amylphenol/formaldehyde resins produced when one mole of p-tert-amylphenol is made to react under acid conditions with one mole of formaldehyde.</td>
<td>For use only at levels not to exceed 2 percent by weight of adhesives complying with §175.105 of this chapter, of pressure-sensitive adhesives complying with §175.125 of this chapter, and of rubber articles complying with §177.2600 of this chapter.</td>
</tr>
<tr>
<td>1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethyl-3-hydroxy-5-methylphenyl)methyl]-4-methylphenyl ester (CAS Reg. No. 57569–40–1).</td>
<td>For use only at levels not to exceed 0.075 percent by weight of olefin polymers complying with §177.1520 of this chapter.</td>
</tr>
<tr>
<td>2-(2 H -Benzotriazol-2-yl)-4,(1-methyl-1-phenylethyl) phenol (CAS Reg. No. 70321–86–7).</td>
<td>For use only: 1. At levels not to exceed 0.5 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter. 2. At levels not to exceed 3.0 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.</td>
</tr>
<tr>
<td>2-(2 H -Benzotriazol-2-yl)-4-(1, 3, 3-tetramethylbutyl) phenol (CAS Reg. No. 3147–75–9).</td>
<td>For use only at levels not to exceed 0.075 percent by weight of olefin polymers complying with §177.1520 of this chapter: Provided, That the finished resins contact food only under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>β, 3(or 4)-Bis(octadecylthio)cyclohexylethane (CAS Reg. No. 37625–75–5); CAS synonym: 1-[beta-(octadecylthio)ethyl]-3(or 4)-[beta-(octadecylthio) cyclohexane.</td>
<td>For use only: 1. At levels not to exceed 0.3 percent by weight of all polymers for use in contact with foods of Types I, II, IV-B, VI, VII-B, and VIII under conditions of use B through H as described in tables 1 and 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of polyolefins complying with §177.1520 of this chapter, for use in contact with food of types III, IV-A, V, VII-A, and IX under conditions of use C through G as described in tables 1 and 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Substances</td>
<td>Limitations</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Bis(2,6,6-tetramethyl-4-piperidinyl) sebacate (CAS Reg. No. 52929-07-9)    | For use only:  
1. In adhesives complying with §175.105 of this chapter.  
2. At levels not to exceed 0.1 percent by weight of pressure-sensitive adhesives complying with §175.125 of this chapter. |
| Bis(2,4-di-tert-butyl-6-methylphenyl)ethyl phosphite (CAS Reg. No. 145650-60-8) | For use only:  
1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 3.2b, 3.4, or 3.5, or 3.1a (where the density of this polymer is at least 0.85 gram per cubic centimeter and less than 0.91 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in table 2 of §176.170(c) of this chapter.  
2. At levels not to exceed 0.1 percent by weight of propylene polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 3.2a, or 3.6 (where the density of each of these polymers is at least 0.94 gram per cubic centimeter), or 5. The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use C (maximum temperature 70 °C) through G described in table 2 of §176.170(c) of this chapter. Provided, that the finished food contact articles have a volume of at least 18.9 liters (5 gallons).  
3. At levels not to exceed 0.01 percent by weight of low-density ethylene polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, or 3.6 (where the density of each of these polymers is less than 0.94 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in table 2 of §176.170(c) of this chapter. Provided, that the average thickness of such polymers in the form in which they contact food shall not exceed 0.001 inch.  
4. As provided in §175.105 of this chapter.  
5. At levels not exceeding 0.1 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with parts 175, 176, 177, and 181 of this chapter.  
6. At levels not exceeding 0.1 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.  
7. At levels not exceeding 0.3 percent by weight of polyetherimide resins complying with §177.1595 of this chapter. |
| 1,2-Bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)-hydrazine (CAS Reg. No. 32697-78-8) | For use only:  
1. As provided in §175.105 of this chapter.  
2. At levels not exceeding 0.1 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.  
3. At levels not exceeding 0.3 percent by weight of polyetherimide resins complying with §177.1595 of this chapter. |
| 2,6-Bis(1-methylheptadecyl)p-cresol ........................................ | For use only:  
1. As provided in §175.105 of this chapter.  
2. At levels not exceeding 0.3 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 3.1, 3.2, or 4. The average thickness of such polymers in the form in which they contact fatty food or food containing more than 8 percent of alcohol shall not exceed 0.004 inch.  
3. As provided in §175.105 of this chapter. |
| 3,9-Bis(2,4-bis(1-methyl-1-phenylethyl)phenoxyl)-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane (CAS Reg. No. 154962-43-8) | For use only:  
1. At levels not to exceed 0.15 percent by weight of all polymers, except as specified below.  
2. At levels not to exceed 0.2 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.  
3. At levels not to exceed 0.3 percent by weight of polyetherimide resins complying with §177.1595 of this chapter.  
4. At levels not exceeding 0.3 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.  
5. At levels not exceeding 0.3 percent by weight of polyetherimide resins complying with §177.1595 of this chapter. |
For use only:

1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter. The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI-A, VI-B, VII-B, and VIII, and under conditions of use B through H described in Table 2 of §176.170(c) of this chapter.

2. At levels not to exceed 0.02 percent by weight of:
   (a) Propylene polymers and copolymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 3.1a, 3.2a, 3.2b, 3.4, or 3.5. The finished polymer may only be used in contact with food of the types identified in §176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of §176.170(c) of this chapter; or
   (b) Ethylene polymers and copolymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, or 3.6 (where the density of each of these polymers is at least 0.94 gram per cubic centimeter), or 5. The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of §176.170(c) of this chapter; provided that the finished food-contact articles have a volume of at least 18.9 liters (5 gallons).

3. At levels not to exceed 0.02 percent by weight of ethylene polymers and copolymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, or 3.6 (where the density of each of these polymers is less than 0.94 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of §176.170(c) of this chapter; provided that the average thickness of such polymers in the form in which they contact food shall not exceed 50 micrometers (0.002 inch).

For use only:

1. At levels not to exceed 0.2 percent by weight of polypropylene complying with §177.1520(c), item 1.1 of this chapter. The finished polymer is to be used in contact with food only under conditions of use D through H described in table 2 of §176.170(c) of this chapter.

2. At levels not to exceed 0.3 percent by weight of polyethylene complying with §177.1520(c) of this chapter, item 2.1, provided that the polymer has a minimum density of 0.94 grams per cubic centimeter and is used in contact with food only under conditions of use D through G described in table 2 of §176.170(c) of this chapter.

3. At levels not to exceed 0.3 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain less than 85 weight percent of polymer units derived from propylene. The finished polymer is to be used in contact with food of types I, II, IV-B, VI-A, VI-B, VI-C, VII-B, and VIII under conditions of use A through H described in tables 1 and 2 of §176.170(c) of this chapter.
4-(6-Bis(cyclohexyl)-α-triazin-2-yl)amino)-2,6-di-tert-butylphenol (CAS Reg. No. 991-84-4).

For use only:
1. At levels not to exceed 0.5 percent by weight, in styrene block copolymers complying with §177.1810 of this chapter; in rosins and resin derivatives complying with §175.300(b)(3)(iv) of this chapter; in can end cement formulations complying with §176.300(b)(3)(xxxii) of this chapter; in side seam cement formulations complying with §175.300(b)(3)(xxix) of this chapter; in petroleum alicyclic hydrocarbon resins and terpene resins complying with §176.170(b)(3) of this chapter; in rosins and resin derivatives complying with §176.170(a)(5) of this chapter; in petroleum alicyclic hydrocarbon resins or their hydrogenated products complying with §176.170(b)(2) of this chapter; in terpene resins complying with §175.300(b)(2)(xii) of this chapter, when such terpene resins are used in accordance with §176.170(b)(1) of this chapter, in resins and polymers complying with §176.180(b) of this chapter; in closures with sealing gaskets complying with §177.1210 of this chapter; in petroleum hydrocarbon resin and rosins and resin derivatives complying with §178.3850 of this chapter; and in reinforced wax complying with §178.3850 of this chapter.

1,3-Butanediol.
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, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent.

For use only:
1. As components of nonfood articles complying with §§175.105 and 177.2600(c)(4)(iii) of this chapter.

1.4±Butanediol.
Butylated, styrenated cresols produced when equal moles of isobutylene, styrene, and a methacryl-para cresol mixture having a no more than 3 °C distillation range including 202 °C are made to react so that the final product meets the following specifications: Not less than 95 percent by weight of total alkylated phenols consisting of 13–25 percent by weight of butylated m- and p-cresols, 26–38 percent by weight of styrenated m- and p-cresols, 37–49 percent by weight of butylated styrenated m- and p-cresols, and not more than 10 percent by weight total of alkylated xyleneols, alkylated o-cresol, alkylated phenol, and alkylated ethylphenol; acidity not more than 0.003 percent; and refractive index at 25 °C of 1.5550–1.5650, as determined by ASTM method D1218–82, "Standard Test Method for Refractive Index and Refractive Dispersion of Hydrocarbon Liquids," 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.

For use only:
1. As provided in §§175.105 and 177.2600 of this chapter.
2. At levels not to exceed 0.5 percent by weight of polyisoprene rubber-modified polystyrene, or olefin polymers complying with §177.1520(c) of this chapter, used in articles that contact food only under the conditions described in table 2 of §176.170(c) of this chapter.
3. At levels not to exceed 0.01 percent by weight in polystyrene and rubber-modified polystyrene complying with §177.1520(c) of this chapter. The polypropylene articles are limited to use in contact with non-fatty foods only.

For use only at levels not to exceed 0.16 percent by weight of ethylene-vinyl acetate-vinyl alcohol copolymers complying with §177.1360(a)(3) and (d) of this chapter.

For use only:
1. As provided in §§175.105 and 177.2600 of this chapter.

4.4′-Bis((α,α-dimethylbenzyl)diphenylamine (CAS Reg. No. 10081–67–1).

For use only:
1. At levels not to exceed 0.3 percent by weight of polystyrene, rubber-modified polystyrene, or olefin polymers complying with §177.1520(c) of this chapter. The polypropylene articles are limited to use in contact with non-fatty foods only.

For use only at levels not to exceed 0.03 percent by weight of polypropylene complying with §177.1520(c) of this chapter. The polypropylene articles are limited to use in contact with non-fatty foods only.

For use only at levels not to exceed 0.01 percent by weight of polystyrene and rubber-modified polystyrene complying with §177.1520(c) of this chapter.

For use only:
1. At levels not to exceed 0.1 percent by weight in polystyrene and rubber-modified polystyrene complying with §177.1640 of this chapter. Provided, That the finished polystyrene and rubber-modified polystyrene polymer contact food only under conditions of use B through G described in table 2 of §176.170(c) of this chapter.

4. In adhesives complying with §175.105 of this chapter; in pressure-sensitive adhesives complying with §175.125 of this chapter; and as provided in §177.2600 of this chapter.

For use only:
1. At levels not to exceed 0.2 percent by weight of the finished cellophane complying with §177.1200 of this chapter.
2. At levels not to exceed 0.1 percent by weight in polystyrene and rubber-modified polystyrene complying with §177.1640 of this chapter. Provided, That the finished polystyrene and rubber-modified polystyrene polymer contact food only under conditions of use B through G described in table 2 of §176.170(c) of this chapter.

For use only at levels not to exceed 0.3 percent by weight of polypolypeylene complying with §177.1520(c) of this chapter. The polypolypeylene articles are limited to use in contact with non-fatty foods only.

For use only at levels not to exceed 0.16 percent by weight of ethylene-vinyl acetate-vinyl alcohol copolymers complying with §177.1360(a)(3) and (d) of this chapter.

For use only:
1. As provided in §§175.105 and 177.2600 of this chapter.
2. At levels not to exceed 1.0 percent by weight of acrylonitrile/butadiene/styrene copolymers. The finished copolymers may be used in contact with food of Types I, II, IV-B, VI-A, VI-B, VII-B, and VIII under conditions of use B through G, as described in tables 1 and 2 of §176.170(c) of this chapter, and with food of Types III, IV-A, V, VI-C, VII-A, and IX under conditions of use C through G.

For use only:
1. As provided in §§175.105 and 177.2600 of this chapter.
2. At levels not to exceed 0.5 percent by weight of polystyrene, rubber-modified polystyrene, or olefin polymers complying with §177.1520(c) of this chapter, used in articles that contact food only under the conditions described in §176.170(c) of this chapter, table 2, under conditions of use C through G.
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-tert-Butyl-α(3-tert-butyl-4-hydroxyphenyl) p-cumenyl bis(p-nonylphenyl) phosphite; the nonyl group is a propylene trimer isomer and the phosphorus content is in the range 3.8–4.0 weight percent.</td>
<td>For use only: 1. As components of nonfood articles complying with §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with §177.1520 of this chapter or in coatings complying with §175.300, §175.320, or §176.170 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch. For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, provided that the finished polymer contacts foods only of the types identified in Categories I, II, IV-B, VI-A and B, VII-B, and VIII in table 1, §176.170 of this chapter. For use only: 1. As provided in §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with §177.1520 of this chapter and for use at levels not to exceed 0.3 percent by weight of polyethylene complying with §177.1520 of this chapter, provided that the finished polypropylene and polyethylene contact food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI-B, and VIII. For use only: 1. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2 except that when used in contact with foods described as types III, IV-A, V, VII-A, and IX in table 1 of §176.170(c) of this chapter, the olefin copolymers may only be used under conditions of use E, F, and G set forth in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight-percent of polymer units derived from propylene). 3. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2.</td>
</tr>
<tr>
<td>2-(3′-tert-Butyl-2′-hydroxy-5′-methyl-phenyl)-5-chlorobenzotriazole with a melting point of 137–141 °C.</td>
<td>For use only: 1. As components of nonfood articles complying with §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with §177.1520 of this chapter or in coatings complying with §175.300, §175.320, or §176.170 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch. For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, provided that the finished polymer contacts foods only of the types identified in Categories I, II, IV-B, VI-A and B, VII-B, and VIII in table 1, §176.170 of this chapter. For use only: 1. As provided in §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with §177.1520 of this chapter and for use at levels not to exceed 0.3 percent by weight of polyethylene complying with §177.1520 of this chapter, provided that the finished polypropylene and polyethylene contact food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI-B, and VIII. For use only: 1. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2 except that when used in contact with foods described as types III, IV-A, V, VII-A, and IX in table 1 of §176.170(c) of this chapter, the olefin copolymers may only be used under conditions of use E, F, and G set forth in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight-percent of polymer units derived from propylene). 3. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2.</td>
</tr>
<tr>
<td>Butyric acid, 3,3-bis(3-tert-butyl-4-hydroxyphenyl)ethylene ester (CAS Reg. No. 32509–66–3).</td>
<td>For use only: 1. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2 except that when used in contact with foods described as types III, IV–A, V, VII–A, and IX in table 1 of §176.170(c) of this chapter, the olefin copolymers may only be used under conditions of use E, F, and G set forth in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight-percent of polymer units derived from propylene). 3. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2.</td>
</tr>
<tr>
<td>Calcium benzoate.</td>
<td>For use only: 1. As components of nonfood articles complying with §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with §177.1520 of this chapter or in coatings complying with §175.300, §175.320, or §176.170 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch. For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, provided that the finished polymer contacts foods only of the types identified in Categories I, II, IV-B, VI-A and B, VII-B, and VIII in table 1, §176.170 of this chapter. For use only: 1. As provided in §§175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with §177.1520 of this chapter and for use at levels not to exceed 0.3 percent by weight of polyethylene complying with §177.1520 of this chapter, provided that the finished polypropylene and polyethylene contact food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI–B, and VIII. For use only: 1. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2 except that when used in contact with foods described as types III, IV–A, V, VII–A, and IX in table 1 of §176.170(c) of this chapter, the olefin copolymers may only be used under conditions of use E, F, and G set forth in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight-percent of polymer units derived from propylene). 3. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2.</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS

Substances | Limitations
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Calcium bis[monoethyl(3,5-di-tert-butyl-4-hydroxy-benzyl)phosphonate] (CAS Reg. No. 65140-91-2). | For use only:
1. At levels not to exceed 0.25 percent by weight of polypropylene that complies with §177.1520(c) of this chapter, items 1.1, 1.2, and 1.3.
2. At levels not to exceed 0.2 percent by weight of polyethylene and olefin copolymers that comply with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 3.6. Finished polymers having a density less than 0.94 gram per cubic centimeter shall be used in contact with food only under conditions of use B through H described in table 2 of §176.170(c) of this chapter.
3. In adhesives complying with §175.105 of this chapter.
4. At levels not to exceed 0.5 percent by weight of pressure-sensitive adhesives complying with §175.125 of this chapter.
5. At levels not to exceed 0.5 percent by weight of rosin and rosin derivatives complying with §175.300(b)(3)(v) of this chapter.
6. At levels not to exceed 0.5 percent by weight of can end cement formulations complying with §175.300(b)(3)(xxxi) of this chapter.
7. At levels not to exceed 0.5 percent by weight of reinforced wax complying with §178.3850.
8. At levels not to exceed 0.3 percent by weight of polyethylene phthalate polymers, complying with §177.1630 of this chapter. Provided, that the finished polymers contact food only under conditions of use B through H described in Table 2 of §176.170(c) of this chapter.

Calcium myristate. | For use only at levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in §177.2470(b)(1) of this chapter.

Calcium ricinoleate | For use only at levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in §177.2470(b)(1) of this chapter.

Calcium stearate. | At levels not to exceed 0.07 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter.

Carbethoxymethyl diethyl phosphonate (CAS Reg. No. 867-13-6). | At levels not to exceed 0.07 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter.

Cerium stereate (CAS Reg. No. 10119-53-6). | For use only at levels not exceeding 0.025 percent by weight of nylon 66T resins complying with §177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250 °F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0012 inch.

Cupric acetate and lithium iodide | For use at levels not exceeding 0.025 percent cupric acetate and 0.005 percent lithium iodide by weight of nylon 66T resins complying with §177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250 °F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0012 inch.

Cuprous iodide | For use at levels not exceeding 0.01 percent cuprous iodide by weight of nylon 66T resins complying with §177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250 °F. The average thickness of such resins in the form in which they contact food shall not exceed 0.001 inch.

Cuprous iodide and cuprous bromide | For use at levels not exceeding 0.0025 percent cuprous iodide and 0.0175 percent cuprous bromide by weight of nylon 66T resins complying with §177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250 °F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.

Cyanoguanidine | For use only at levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in §177.2470(b)(1) of this chapter.
### § 178.2010

Substances | Limitations
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Cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806–34–6) (which may contain not more than 1 percent by weight of trisopropanolamine (CAS Reg. No. 122–20–3)); the phosphorus content is in the range of 7.8 to 8.2 weight percent. | For use only at levels not to exceed 0.1 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter that contact food under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter. 1. At levels not to exceed 0.05 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4; Provided, That the finished polymers contact food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, IV, VI, VII-B, and VIII. The concentration of this additive and any other permitted antioxidants in the finished food-contact article shall not exceed a total of 0.5 milligram per square inch of food-contact surface. 2. At levels not to exceed 0.033 percent by weight of rigid polyvinyl chloride, under conditions of use A through H described in table 2 of §176.170(c) of this chapter. 3. At levels not to exceed 0.05 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1 and 3.2, that contact food Types I, II, VI-A, VII-B, and VIII described in table 1 of §176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter. 4. At levels not to exceed 0.20 percent by weight of polystyrene and/or rubber modified polystyrene complying with §177.1640 of this chapter that contact food under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter. 5. At levels not to exceed 0.05 percent by weight, including the level that may be contributed by its presence at 6 percent in the item “butylated, styrenated cresols * * *” listed in this paragraph; and further provided that the finished olefin polymers are intended for contact with foods, except those containing more than 8 percent alcohol. 6. At levels not to exceed 0.05 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter and under conditions of use B through H described in table 2 of §176.170(c) of this chapter. 7. At levels not to exceed 0.05 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter and under conditions of use B through H described in table 2 of §176.170(c) of this chapter.

Cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806–34–6) (which may contain not more than 1 percent by weight of trisopropanolamine (CAS Reg. No. 122–20–3)); the phosphorus content is in the range of 7.8 to 8.2 weight percent. | For use only at levels not to exceed 0.25 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 2.1, and 3.1. 2. At levels not to exceed 0.25 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 2.2, that contact food Types I, II, VI-A, VII-B, and VIII described in table 1 of §176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter. 3. At levels not to exceed 0.15 percent by weight of olefin polymers complying with §177.1520, items 1.1 and 3.2, that contact food Types I, II, VI-A, VII-B, and VIII described in table 1 of §176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.

Didodecyl thiiodipropionate having a melting point of 59–62 °C as determined by ASTM method E324–79. "Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals," and a saponification value in the range 176–183 as determined by ASTM method D1962–67 (Reapproved 1979), "Standard Test Method for Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids." which are 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. | For use only at levels not to exceed 0.3 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with applicable regulations in parts 175, 176, 177, and 181 of this chapter, under conditions of use C through H as described in table 2 of §176.170(c) of this chapter. 1. At levels not to exceed 0.3 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with applicable regulations in parts 175, 176, 177, and 181 of this chapter, under conditions of use C through H as described in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.033 percent by weight of rigid polyvinyl chloride, under conditions of use A through H as described in table 2 of §176.170(c) of this chapter.

Didodecyl–1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylate (CAS Reg. No. 36265–41–5). | For use only at levels not to exceed 0.3 percent by weight in rigid polymer articles modified in accordance with §178.3790 that contact food, under conditions of use E, F, and G described in table 2 of §176.170 of this chapter.

2.6-Di(α-methyl benzyl)-4-methyl phenol [Chemical Abstracts Service Registry No. 1817–68–1]. | For use only at levels not to exceed 0.3 percent by weight in rigid polymer articles modified in accordance with §178.3790 that contact food, under conditions of use E, F, and G described in table 2 of §176.170 of this chapter.

2,4-Dimethyl-6-(1-methylpentadecyl)phenol (CAS Reg. No. 134701–20–5). | For use only:

Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol (CAS Reg. No. 65467–77–5). | For use only:

4',4'-Cyclohexylidenebis(2-cyclohexylphenol) | For use only:


### Substances

**Dimethyltin/monomethyltin**
- Isooctyl mercaptocacetate consisting of 5 to 90 percent by weight of monomethyltris(isooctyl mercaptocacetate) (CAS Reg. No. 57583-34-3) and 10 to 95 percent by weight of dimethyl tris(2-ethylhexyl mercaptocacetate) (CAS Reg. No. 26636-01-1) or dimethyltris(2-ethylhexyl mercaptocacetate) (CAS Reg. No. 57583-35-4), and no more than 0.4 percent by weight of trimethyltin compounds, and having the following specifications: Tin content (as Sn) in the range of 15 to 21 percent and mercaptosulfur content in the range of 11 to 13.5 percent. Other alkyltin compounds are not to exceed 20 ppm.

- Di(n-octyl)tin bis(2-ethylhexyl maleate) [CAS Reg. No. 10039-33-5] having 12.5 to 15.0 percent by weight of tin (Sn) and having a saponification number of 260 to 280. The additive is made from di(n-octyl)tin oxide meeting the specifications of §178.2650(a)(1).
- N,N′-Diphenylthiourea ............................................. For use only:
  1. At levels not to exceed 0.5 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1980 of this chapter.
  2. At levels not to exceed 0.5 percent by weight of vinyl chloride-vinyl acetate copolymers containing not more than 20 molar percent of vinyl acetate.
- 2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-hexyloxyphenol (CAS Reg. No. 147315-50-2).
- 2,6-Di-tert-butyl-4-ethylphenol ................................. For use only in contact with nonalcoholic foods:
  1. At levels not exceeding 0.04 mg/in² of food contact surface and not exceeding 0.1 percent by weight in ethylene polymers and copolymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; §177.1340; and §177.1350 of this chapter.

### Limitations

**For use only at levels not to exceed 2 percent by weight:**
1. In rigid polystyrene and in rigid polystyrene copolymers complying with §177.1950 of this chapter or §177.1980 of this chapter for use in contact with food of Types I, II, III, IV (except liquid milk), V, VI, VII, VIII, and IX described in table 1 of §176.170(c) of this chapter under conditions of use C through G described in table 2 of §176.170(c) of this chapter at temperatures not to exceed 88°C (190°F).

**For use only at levels not to exceed 0.5 percent by weight of acrylonitrile copolymers complying with §§177.1020 and 177.1030 of this chapter and used in contact with all food types under conditions of use C through G described in table 2 of §176.170(c) of this chapter.**

**Finished food-contact articles containing this additive shall meet the extracts limitations prescribed in §176.170(c) of this chapter.**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethyltin/monomethyltin isoctyl mercaptocacetate consisting of 5 to 90 percent by weight of monomethyltris(isooctyl mercaptocacetate) (CAS Reg. No. 57583-34-3) and 10 to 95 percent by weight of dimethyl tris(2-ethylhexyl mercaptocacetate) (CAS Reg. No. 26636-01-1) or dimethyltris(2-ethylhexyl mercaptocacetate) (CAS Reg. No. 57583-35-4), and no more than 0.4 percent by weight of trimethyltin compounds, and having the following specifications: Tin content (as Sn) in the range of 15 to 21 percent and mercaptosulfur content in the range of 11 to 13.5 percent. Other alkyltin compounds are not to exceed 20 ppm.</td>
<td>For use only at levels not to exceed 2 percent by weight: 1. In rigid polystyrene and in rigid polystyrene copolymers complying with §177.1950 of this chapter or §177.1980 of this chapter for use in contact with food of Types I, II, III, IV (except liquid milk), V, VI, VII, VIII, and IX described in table 1 of §176.170(c) of this chapter under conditions of use C through G described in table 2 of §176.170(c) of this chapter at temperatures not to exceed 88°C (190°F).</td>
</tr>
<tr>
<td>Di(n-octyl)tin bis(2-ethylhexyl maleate) [CAS Reg. No. 10039-33-5] having 12.5 to 15.0 percent by weight of tin (Sn) and having a saponification number of 260 to 280. The additive is made from di(n-octyl)tin oxide meeting the specifications of §178.2650(a)(1).</td>
<td>For use only at levels not to exceed 0.5 percent by weight of acrylonitrile copolymers complying with §§177.1020 and 177.1030 of this chapter and used in contact with all food types under conditions of use C through G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>N,N′-Diphenylthiourea ............................................. For use only: 1. At levels not to exceed 0.5 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1980 of this chapter. 2. At levels not to exceed 0.5 percent by weight of vinyl chloride-vinyl acetate copolymers containing not more than 20 molar percent of vinyl acetate.</td>
<td>For use only: 1. At levels not to exceed 0.5 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1980 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polyester elastomers complying with §177.1590 of this chapter. 3. At levels not to exceed 0.5 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter, in contact with food under conditions of use A through H described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-hexyloxyphenol (CAS Reg. No. 147315-50-2).</td>
<td>For use only in contact with nonalcoholic foods: 1. At levels not exceeding 0.04 mg/in² of food contact surface and not exceeding 0.1 percent by weight in ethylene polymers and copolymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; §177.1340; and §177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall not exceed 0.0025 in. 2. At levels not exceeding 0.04 mg/in² of food contact surface in ethylene polymers and copolymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; §177.1340; and §177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall be greater than 0.0025 in but shall not exceed 0.025 in.</td>
</tr>
</tbody>
</table>
Substances Limitations

3,5-Di-tert-butyl-4-hydroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-s-triazine-2,4,6-(1H,3H,5H)-trione (CAS Reg. No. 34137-09-2).

For use only:
1. At levels not to exceed 0.5 percent by weight of polypropylene complying with §177.1520 of this chapter in articles that contact food not in excess of high temperature heat-sterilized condition of use A described in §176.170(c) of this chapter, table 2.
2. At levels not to exceed 0.5 percent by weight of polyethylene complying with §177.1520 of this chapter in articles that contact food not in excess of high temperature heat-sterilized condition of use A described in §176.170(c) of this chapter, table 2.
3. In adhesives complying with §175.105 of this chapter.
4. At levels not to exceed 0.25 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0.
5. At levels not to exceed 2 percent by weight of polyester elastomers, complying with §177.1590 of this chapter, in contact with dry food only, and finished rubber articles for repeated use, complying with §177.2600 of this chapter, in contact with all foods, at temperatures not to exceed 150 °F.

Di-tert-butyl-m-cresyl phosphonite condensation product with biphenyl (CAS Reg. No. 178358-58-2) produced by the condensation of 4,6-di-tert-butyl-m-cresol with the Friedel-Crafts addition product (phosphorus trichloride and biphenyl) so that the food additive has a minimum phosphorus content of 5.0 percent.

For use only:
1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 2.1, 2.2, 3.1(a), 3.1(b), 3.2(a), or 3.2(b).

Di-tert-butylphenyl phosphonite condensation product with biphenyl (CAS Reg. No. 119345-01-6) produced by the condensation of 2,4-di-tert-butylphenol with the Friedel-Crafts addition product (phosphorus trichloride and biphenyl) so that the food additive has a minimum phosphorus content of 5.4 percent, an acid value not exceeding 10 mg KOH/gm, and a melting range of 85 °C to 110 °C (185 °F to 230 °F).

For use only:
1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 3.2b, 3.3a, 3.3b, 3.4, 3.5, and 3.1a (where the density is not less than 0.85 gram per cubic centimeter and not more than 0.91 gram per cubic centimeter); and 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, and 3.6 (where the density is not less than 0.94 gram per cubic centimeter) and 5.
2. At levels not to exceed 0.1 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.
3. At levels not to exceed 0.2 percent by weight of polystyrene and 0.3 percent by weight of rubber-modified polystyrene complying with §177.1640 of this chapter.
4. At levels not to exceed 0.15 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1a, 3.1b, 3.2a, 3.4, 3.5, and 3.6 (where the polyethylene component has a density less than 0.94 gram per cubic centimeter).
5. At levels not to exceed 0.1 percent by weight of repeated use rubber articles complying with §177.2600 of this chapter.

2,4-Di-tert-butylphenyl-3,5-di-tert-butyl-4-hydroxybenzoate (CAS Reg. No. 4221-80-1).

For use only:
1. At levels not to exceed 0.6 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1: (1) when used in single-use articles that contact food of types I, II, IV-B, VI-A, VI-B, VII-B, and VIII, identified in table 1 of §176.170(c) of this chapter; and (2) when used in repeated-use articles that contact food of types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter. The additive is used under conditions of use B through H described in table 2 of §176.170(c) of this chapter.
2. At levels not to exceed 0.25 percent by weight of olefin polymers having a density of not less than 0.94 gram per cubic centimeter and complying with §177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2: (1) when used in single-use articles that contact food of types I, II, IV-B, VI-A, VI-B, VII-B, and VIII, identified in table 1 of §176.170(c) of this chapter; and (2) when used in repeated-use articles that contact food of types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter. The additive is used under conditions of use B through H described in table 2 of §176.170(c) of this chapter.
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>2,4-Di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate (CAS Reg. No. 123968-25-2).</td>
<td>For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with §177.1520 of this chapter in contact with food under conditions of use D through G as described in Table 2 of §176.170(c) of this chapter, except that polypropylene containing the additive at levels not to exceed 0.075 percent by weight may contact food under conditions of use A through H described in Table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 1.0 percent by weight of styrene block polymers complying with §177.1810 of this chapter. The additive is used under conditions of use D through G as described in Table 2 of §176.170(c) of this chapter. 3. At levels not to exceed 1.0 percent by weight of polystyrene and rubber modified polystyrene complying with §177.1640 of this chapter in contact with food under conditions of use D through G as described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>N,N″-1,2-Ethanediybis[N-(3-[1,2,2,6,6-pentamethyl-4-piperidinyl]-amino)-1,3,5-triazin-2-ylamino]propyl-N,N″-dibuty-N,N″-dibutyl-N,N″-tetramine (CAS Reg. No. 106990-43-6).</td>
<td>For use only: 1. At levels not to exceed 0.06 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1a, 1.1b, 1.2, or 1.3. The finished polymers may only be used in contact with food of the Types III, IV-A, V, VI-C, VII-A, and IX as described in table 1 of §176.170(c) of this chapter, and under conditions of use A through H as described in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.08 percent by weight of olefin polymers complying with §177.1520(c) of this chapter. The finished polymers may only be used in contact with food of the Types I, II, IV-B, VI-A, VI-B, VII-B, and VIII as described in table 1 of §176.170(c) of this chapter, and under conditions of use A through H as described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Ethylenebis(oxyethylene)-bis-(3-tert-butyl-4-hydroxy-5-methylhydrocinnamate) (CAS Reg. No. 36443-68-2).</td>
<td>1. At levels not to exceed 0.3 percent by weight of polystyrene and/or rubber modified polystyrene polymers complying with §177.1640 of this chapter. 2. At levels not to exceed 0.3 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with applicable regulations in parts 175, 176, 177, and 181 of this chapter. 3. At levels not to exceed 0.75 percent by weight of polycosymethylene copolymers used in accordance with §177.2470 of this chapter. The finished articles shall not be used for foods containing more than 15 percent alcohol. 4. At levels not to exceed 0.25 percent by weight of polycosymethylene homopolymers used in accordance with §177.2480 of this chapter. The finished articles shall not be used for foods containing more than 15 percent alcohol. 5. At levels not to exceed 0.2 percent by weight of rigid vinyl chloride plastics prepared from vinyl chloride homopolymers and/or vinyl chloride copolymers used in accordance with a prior sanction or applicable regulations in parts 175, 176, and 177 of this chapter. The vinyl chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinyl chloride. 6. At levels not to exceed 0.1 percent by weight of vinylidene chloride homopolymers and/or vinylidene chloride copolymers used in accordance with a prior sanction or applicable regulations in parts 175, 176, and 177 of this chapter. The vinylidene chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinylidene chloride. 7. In adhesives used in accordance with §175.105 of this chapter.</td>
</tr>
<tr>
<td>Substances</td>
<td>Limitations</td>
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</tbody>
</table>
| 2,2′-Ethylidenebis(4,6-di-tert-butylphenol) (CAS Reg. No. 35958-30-6). | For use only:  
1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 3.1, or 3.2 (where the polymers complying with items 3.1 and 3.2 contain primarily polymer units derived from propylene).  
2. At levels not to exceed 0.05 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 2.1, 2.2, or 2.3. The finished polymers are to be used only under conditions of use B through H described in table 2 of §176.170(c) of this chapter.  
3. At levels not to exceed 0.075 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 2.1, 2.2, or 2.3 (where the density of each of these polymers is not less than 0.94 g/cc) and item 3.1 or 3.2 (where each of these polymers contains primarily polymer units derived from ethylene).  
4. At levels not to exceed 0.05 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 3.3, 3.4, 3.5, or 4.  
5. At levels not to exceed 0.1 percent by weight of ethylene vinyl acetate copolymers complying with §177.1350 of this chapter and under conditions of use C through G described in table 2 of §176.170(c) of this chapter.  
6. At levels not to exceed 0.1 percent by weight of rigid or semirigid polyvinyl chloride and under conditions of use B through H described in table 2 of §176.170(c) of this chapter.  
7. At levels not to exceed 0.2 percent by weight of acrylonitrile-butadiene-styrene copolymers containing less than 30 percent by weight of acrylonitrile and under conditions of use D through G described in table 2 of §176.170(c) of this chapter.  
8. At levels not to exceed 0.1 percent by weight of polystyrene complying with §177.1640 of this chapter and under conditions of use D through G described in table 2 of §176.170(c) of this chapter.  
9. At levels not to exceed 0.05 percent by weight of rubber-modified polystyrene complying with §177.1640 of this chapter.  
10. In adhesives complying with §175.105 of this chapter. |
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<table>
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| 2,2'-Ethylidenbis(4,6-di-tert-butylphenyl)fluorophosphonite (CAS Reg. No. 118337–09–0). | For use only:  
| 1. As provided in § 175.105 of this chapter.  
| 2. In all polymers used in contact with food of types I, II, IV–B, VI–A, VI–B, VII–B, and VIII, under conditions of use B through H described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.25 percent by weight of polymers.  
| 3. In polypropylene complying with § 177.1520(c) of this chapter, item 1.1, in contact with food of types III, IV–A, V, VII–A, and IX, under:  
| (a) Conditions of use B through H described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.25 percent by weight of the polymer; or  
| (b) Condition of use A, limited to levels not to exceed 0.1 percent by weight of the polymer; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch).  
| 4. In olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1a or 3.2a, and containing not less than 85 percent by weight of polymer units derived from propylene, in contact with food of types III, IV–A, V, VII–A, and IX, and under:  
| (a) Conditions of use C through G, described in Tables 1 and 2 of § 176.170(c) of this chapter, limited to levels no greater than 0.2 percent by weight of the copolymers; or  
| (b) Conditions of use A, B, and H, limited to levels no greater than 0.1 percent by weight of the olefin copolymers; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch).  
| 5. In olefin polymers complying with § 177.1520(c) of this chapter, items 1.2 or 1.3 in contact with food of types III, IV–A, V, VII–A, and IX, under conditions of use A through H, described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.1 percent by weight of the polymer; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch).  
| 6. In polyethylene complying with § 177.1520(c) of this chapter, items 2.1 or 2.2, having a density of not less than 0.94, in contact with food of types III, IV–A, V, VII–A, and IX, and under:  
| (a) Conditions of use B through H, described in Tables 1 and 2 of § 176.170(c) of this chapter limited to levels not to exceed 0.2 percent by weight of the polymers; or  
| (b) Condition of use A, described in Tables 1 and 2 of § 176.170(c) of this chapter, limited to levels not to exceed 0.1 percent by weight of the polymer; provided that the food-contact surface has an average thickness not exceeding 125 micrometers (0.005 inch).  
| 7. In olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.2a, or 3.2b, containing not less than 85 percent by weight of polymer units derived from ethylene and having a density of not less than 0.94, in contact with food of types III, IV–A, V, VII–A, and IX, and under:  
| (a) Conditions of use C through G, described in Tables 1 and 2 of § 176.170(c) of this chapter limited to levels not to exceed 0.2 percent by weight of the copolymers; or  
| (b) Conditions of use A, B, and H, limited to levels not to exceed 0.1 percent by weight of the copolymers; provided that the food-contact surface has an average thickness not exceeding 125 micrometers (0.005 inch).  
| 8. In olefin polymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.2a, or 3.2b containing not less than 85 percent by weight of polymer units derived from ethylene, in contact with food of types III, IV–A, V, VII–A, and IX, under conditions of use A through H, as described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.1 percent by weight of the copolymer; provided that the food-contact surface has an average thickness not exceeding 75 micrometers (0.003 inch).  
| 9. In polyethylene phthalate polymers complying with § 177.1630 of this chapter in contact with food of types III, IV–A, V, VII–C, VII–A, and IX, and under:  
| (a) Conditions of use B through H, described in tables 1 and 2 of § 176.170(c) of this chapter, limited to levels not to exceed 0.3 percent by weight of the polymers; or  
| (b) Condition of use A with food of types III, IV–A, V, VII–A, and IX, and limited to levels not to exceed 0.1 percent by weight of the polymers; provided that the film thickness does not exceed 675 micrometers (0.035 inch).  

Hexadecyl 3,5-di-tert-butyl-4-hydroxybenzoate (CAS Reg. No. 67845–93–6). For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter.
### Hexamethylenebis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2)

For use only:
1. As provided in §177.2470(b)(1) and §177.2480(b)(1) of this chapter.
2. In adhesives complying with §175.105 of this chapter.
3. At levels not to exceed 1 percent by weight in pressure-sensitive adhesives complying with §175.125 of this chapter.
4. At levels not to exceed 1 percent by weight in can end cement formulations complying with §175.300(b)(3)(xxxii) of this chapter.
5. At levels not to exceed 1 percent by weight in petroleum alicyclic hydrocarbon resins, polyamide resins, and terpene resins complying with §175.320 of this chapter.
6. At levels not to exceed 1 percent by weight in rosin and rosin derivatives when used in accordance with §176.170(a)(5) of this chapter.
7. At levels not to exceed 1 percent by weight in terpene resins complying with §175.300(b)(3)(xi) of this chapter, when such terpene resins are used in accordance with §176.170(b)(1) of this chapter.
8. At levels not to exceed 1 percent by weight in resins and polymers authorized for use in accordance with §176.180 of this chapter.
9. At levels not to exceed 1 percent by weight in closures with sealing gaskets complying with §177.1210 of this chapter.
10. At levels not to exceed 1 percent by weight in rubber articles intended for repeated use complying with §177.2600 of this chapter.
11. At levels not to exceed 1 percent by weight in closures with sealing gaskets complying with §177.2600 of this chapter.
12. At levels not to exceed 1 percent by weight in petroleum hydrocarbon resin and rosins and rosin derivatives used in accordance with §178.3800 of this chapter.
13. At levels not to exceed 1 percent by weight in reinforced wax complying with §178.3850 of this chapter.

### N,N′-Hexamethylenebis (3,5-di-tert-butyl-4-hydroxyhydrocinnamamide) (CAS Reg. No. 23128-74-7)

For use only:
1. At levels not to exceed 1 percent by weight of nylon resins complying with §177.1500(b) of this chapter, items 1 through 8, that contact food only of the types identified in categories in §176.170(c) of this chapter, table 1 except VI-A and VI-C.
2. At levels not to exceed 0.75 percent by weight of nylon 12 resins complying with §177.1500(b) of this chapter, item 9, that contact food only of the types identified in categories in §176.170(c) of this chapter, table 1, except VI-A and VI-C.
3. At levels not to exceed 0.6 percent by weight of polyester resins complying with §175.300(b)(3)(v) of this chapter.
4. At levels not to exceed 0.6 percent by weight of closures with sealing gaskets complying with §177.1210 of this chapter.
5. At levels not to exceed 0.6 percent by weight of repeated use rubber articles complying with §177.2600 of this chapter.
6. At levels not to exceed 0.5 percent by weight of polyoxymethylene copolymer complying with §177.2470 of this chapter.
7. At levels not to exceed 0.5 percent by weight of polyoxymethylene homopolymer complying with §177.2480 of this chapter.

### 1,6-Hexanediamine, N,N′-bis(2,2,6,6-tetramethyl-4-pipentidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated (CAS Reg. No. 193098-40-7)

For use only as a stabilizer at levels not to exceed 0.3 percent by weight of olefin polymers complying with §177.1520(c)(1) of this chapter. The finished polymers are to contact food only under conditions of use C, D, E, F, and G, as described in Table 2 of §176.170(c) of this chapter. Provided that the finished food-contact articles have a volume of at least 18.9 liters (5 gallons).


For use only at levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c)(1) of this chapter. Provided that the finished polymer contacts food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, VII-B and VIII under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter.
<table>
<thead>
<tr>
<th>Substances</th>
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</table>
| 2′-Hydroxy-5′-methylphenylbenzotriazole meeting the following specification: melting point 126°–132 °C (258.8°–269.6 °F) (CAS Reg. No. 2440–22–4). | For use only:  
1. As component of nonfood articles complying with §177.1010 of this chapter.  
2. At levels not to exceed 0.25 percent by weight of rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with §177.1980 of this chapter.  
3. In polystyrene that complies with §177.1640 of this chapter and that is limited to use in contact with dry food of Type VIII described in table 1 of §176.170(c) of this chapter.  
4. At levels not to exceed 0.25 percent by weight of polystyrene and/or rubber-modified polystyrene polymers complying with §177.1640 of this chapter intended to contact nonalcoholic food. Provided, That the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 90 weight percent of total polymer units derived from styrene monomer.  
5. At levels not to exceed 0.5 percent by weight of polycarbonate resins complying with §177.1580 of this chapter. Provided, That the finished polycarbonate resins contact food only of Types I, II, III, IV, V, VI–A, VI–B, VII, VIII, 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.  
6. At levels not to exceed 0.5 percent by weight of ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers complying with §177.1315 of this chapter and of ethylene phthalate polymers complying with §177.1630 of this chapter and that contact food only under conditions of use D through G described in table 2, §176.170(c) of this chapter. |
| 2-Hydroxy-4-n-octoxy-benzophenone ................................................. | For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4: Provided, That the finished polymer contacts food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, IV–B, VII–B, and VIII, and under the conditions of use B through H described in table 2 of §176.170(c) of this chapter. |
| 4′-Isopropyldienediphenol alkyl(C<sub>12–15</sub>) phosphites; the phosphorus content is in the range of 5.2–5.6 weight percent. | For use only at levels not exceeding 1.0 percent by weight in rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with §§177.1950, 177.1970 or 177.1980 of this chapter, and used in contact with food, except milk, only under the conditions described in §176.170(c) of this chapter, table 2, under conditions of use D through G. |
| Magnesium salicylate .......................................................................... | For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with §177.1980 of this chapter. Provided, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers. |
| 2-Methyl-4,6-bis{(octylthio)methyl} phenol (CAS Reg. No. 110553–27–0).    | For use only:  
1. In adhesives complying with §175.105 of this chapter.  
2. At levels not to exceed 0.5 percent by weight of can-end cements and side-seam cements complying with §175.300(b)(xxx) and (xxxii) of this chapter.  
3. At levels not to exceed 1 percent by weight of pressure sensitive adhesives complying with §175.125 of this chapter petroleum alicyclic hydrocarbon resins complying with §176.170 of this chapter, resins and polymers complying with §176.180 of this chapter, and closures with sealing gaskets complying with §177.1210 of this chapter.  
4. At levels not to exceed 1.7 percent by weight of the finished rubber products complying with §177.2600 of this chapter.  
5. At levels not to exceed 0.1 percent by weight of petroleum alicyclic hydrocarbon resins complying with §175.320 of this chapter; rubber-modified polystyrene complying with §177.1640 of this chapter; and petroleum hydrocarbon resins and rosins and rosin derivatives complying with §178.3800 of this chapter.  
6. At levels not to exceed 0.2 percent by weight of styrene block polymers complying with §177.1810 of this chapter that contact food of Types I, II, IV–B, VI, VII–B, and VIII described in table 1, §176.170(c) of this chapter, only under conditions of use C through H described in table 2, §176.170(c) of this chapter. |
<table>
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<tr>
<th>Substances</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>2,2′-Methylenebis(4,6-di-tert-butylphenyl)(2-ethylhexyl)phosphite (CAS Reg. No. 126050-54-2)</td>
<td>For use only at levels not to exceed 0.25 percent by weight of polypropylene complying with §177.1520 of this chapter. The finished polymers may only be used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, IV-B, VI-B, VII-B, and VIII under conditions of use B through H described in table 2, §176.170(c) of this chapter, and with food of the types identified in §176.170(c) of this chapter, table 1, under Categories III, IV-A, V, VI-A, VII-C, VII-A, and IX under conditions of use C through G described in table 2, §176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>
| 2,2′-Methylenebis(6-tert-butyl-4-ethylphenol) | For use only:  
1. In acrylonitrile-butadiene-styrene copolymers at levels not to exceed 0.6 percent by weight of the copolymer.  
2. In semirigid and rigid acrylic and modified acrylic plastics complying with §177.1010 of this chapter at levels not to exceed 0.1 percent by weight of the plastic. |
| 4,4′-Methylenebis(2,6-di-tert-butyl-phenol) | For use only:  
1. As provided in §175.105 of this chapter.  
2. At levels not to exceed 0.25 percent by weight of petroleum hydrocarbon resins used in compliance with regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter.  
3. At levels not to exceed 0.5 percent by weight of terpene resins used in compliance with regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter.  
4. At levels not to exceed 0.5 percent by weight of polyethylene used in rubber articles complying with §177.1520 of this chapter: Provided, that the rubber end product contacts foods only of the types identified in Categories I, II, IV-B, VI, VII-B, and VIII in table 1, §176.170(c) of this chapter.  
5. At levels not to exceed 0.25 percent by weight of petroleum hydrocarbon resins used in contact with food of the types identified in Categories I, II, IV-B, VI, VII-B, and VIII in table 1, §176.170(c) of this chapter.  
6. At levels not to exceed 0.5 percent by weight of acrylonitrile-butadiene-styrene copolymers that comply with §177.1020 of this chapter when used in articles that contact food only under conditions of use E, F, and G as described in table 2, §176.170(c) of this chapter. |
| 2,2′-Methylenebis(6-(1-methylcyclo-hexyl)-p-cresol) | For use only:  
1. As provided in §177.1210 of this chapter.  
2. At levels not to exceed 0.2 percent by weight of polyethylene used in rubber articles complying with §177.1520 of this chapter: Provided, that the finished polyethylene contacts foods only of the type identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI-B, and VIII.  
3. In polyethylene complying with §177.1520 of this chapter: Provided, that the finished polyethylene contacts foods only of the types identified in §176.170(c) of this chapter, table 1, under Categories III, IV, V, VI-A, VII, and IX, and only at temperatures not to exceed room temperature: And further provided, That percentage concentration of the antioxidant in the polyethylene, when multiplied by the thickness in inches of the finished polyethylene, shall not be greater than 0.0005. |
| 2,2′-Methylenebis(4-methyl-6-nonylphenol) and 2,6-bis(2-hydroxy-3-nonyl-5-methyl-benzyl)-p-cresol mixtures (varying proportions) | For use only in acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods. |
Substances Limitations

Methyltin-2-mercaptoethyleolate sulfide, which is defined as one or more of the following:

1. 9-Octadecenoic acid (Z)-, 2-mercaptoethyl ester, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 68442-12-6);
2. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, 2-mercaptoethyl decanoate, 2-mercaptoethyl octanoate, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 151436-98-5); or
3. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 201687-67-2); and which has the following specifications: Tin content (as Sn) 5 to 21 percent by weight; mercaptosulfur content 5 to 13 percent by weight; acid value no greater than 4.

Methyltin-2-Mercaptoethyleolate sulfide may also be used with one or more of the following optional substances:
1. 1a 2-Mercaptoethyl oleate (CAS Reg. No. 59118-78-4),
1. 1b 2-Mercaptoethyl tallate (CAS Reg. No. 68440-24-4),
1. 1c 2-Mercaptoethyl octanoate (CAS Reg. No. 57813-59-9),
1. 1d 2-Mercaptoethyl decanoate (CAS Reg. No. 68928-33-6), alone or in combination; not to exceed 40 percent by weight of the stabilizer formulation;
2. 1 2-Mercaptoethanol (CAS Reg. No. 60-24-2); Not to exceed 2 percent by weight of the stabilizer formulation.
3. 1 Mineral oil (CAS Reg. No. 8012-95-1); Not to exceed 40 percent by weight of the stabilizer formulation.
4. 1 Butylated hydroxytoluene (CAS Reg. No. 128-37-0); Not to exceed 5 percent by weight of the stabilizer formulation.
The total of the optional substances (1.1a through 4.1) shall not exceed 60 percent by weight of the stabilizer formulation.

Nylon 66/610/6 terpolymer (see § 177.1500 of this chapter for identification)

For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter.

Nylon 612/6 copolymer (CAS Reg. No. 51733-10-9), weight ratio 6/1.

For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1).
Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3).

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For use only:

1. At levels not exceeding 0.25 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4.

2. As provided in §§175.105 and 177.1010(a)(5) of this chapter.

3. At levels not exceeding 0.25 percent by weight of polystyrene and/or rubber-modified polystyrene polymers complying with §177.1640 of this chapter, except that the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 85 weight percent of total polymer units derived from styrene monomer.

4. At levels not to exceed 0.5 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with prior sanction or regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter.

5. At levels not exceeding 0.25 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.4 and 3.5 as follows: (a) item 3.4, Provided, That the finished copolymer contacts foods only of types identified in §176.170(c) of this chapter, table 1, under Categories I, II, III, IV–B, VI, VII, VIII, and IX; (b) item 3.5, Provided, That the finished copolymer contacts non-fatty foods only of types identified in §176.170(c) of this chapter, table 1, under Categories I, II, IV–B, VI, VII–B, and VIII.

6. At levels not exceeding 0.05 percent by weight of modified semi-rigid and rigid vinyl chloride plastics modified with methacrylate-butadiene-styrene copolymers in accordance with §178.3790.

7. At levels not exceeding 0.2 percent by weight of rigid polyvinyl chloride.

8. At levels not to exceed 0.3 percent by weight of polycarbonate resins that comply with §177.1580 and that contact food only under conditions of use E, F, and G described in table 2, §176.170(c) of this chapter.

9. At levels not exceeding 0.1 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.

10. At levels not to exceed 0.2 percent by weight of nitrile rubber-modified acrylonitrile-methyl acrylate copolymers that comply with §177.1480 of this chapter when used in articles that contact food only under conditions of use D, E, F, and G described in table 2, §176.170(c) of this chapter.

11. At levels not exceeding 0.3 percent by weight of styrene block polymers complying with §177.1810 of this chapter when used in articles that contact food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, IV–B, VI, VII–B, and VIII, and under conditions of use D, E, F, and G described in table 2 of §176.170(c) of this chapter.

12. At levels not exceeding 0.2 percent by weight of vinylidene chloride homopolymers and/or vinylidene chloride copolymers complying with applicable regulations in parts 175, 176, 177, 179, and 181 of this chapter. The vinylidene chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinylidene chloride.

13. At levels not exceeding 0.025 percent by weight of chlorinated isobutylene-isoprene copolymers complying with §177.1420(a)(3) of this chapter.

14. At levels not exceeding 0.5 percent by weight of the finished rubber article complying with §177.2600 of this chapter.
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</table>
| 7-Oxa-3,20-diazadispiro[5.1.11.2]-heneicosan-21-lymerized (CAS Reg. No. 202483-55-4). | For use only:  
1. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from ethylene; in contact with all types of food described in Table 1 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) when in contact with food of types III, IV–A, V, VII–A, and IX described in Table 1 of § 176.170 of this chapter.  
2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 2.1, 2.2, 3.1, and 3.2, having a density of not less than 0.94 gram/milliliter, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from ethylene; in contact with food only under conditions of use C, D, E, F, and G, described in Table 2 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) when in contact with food of types III, IV–A, V, VII–A, and IX, described in Table 1 of § 176.170 of this chapter.  
3. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 2.1, 2.2, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 4.0, having a density of less than 0.94 gram/milliliter, in contact with food only under conditions of use D, E, F, and G, described in Table 2 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) except that, films and molded articles containing not more than 0.2 percent by weight of the stabilizer may contact aqueous food of types I, II, IV–B, VI, VIII, described in Table 1 of § 176.170 of this chapter with no restrictions on the amount of food contacted. |
| Oxidized bis (hydrogenated tallow alkyl) amines | For use only:  
1. At levels not to exceed 0.1 percent by weight of polypropylene polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 3.1a (density not less than 0.85 gram per cubic centimeter and less than 0.91 gram per cubic centimeter), 3.2b, 3.4, and 3.5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VII described in table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in table 2 of § 176.170(c) of this chapter and with food types III, IV–A, V, VII–A, and IX described in table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in table 2 of § 176.170(c) of this chapter.  
2. At levels not to exceed 0.075 percent by weight of high-density polyethylene polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (density not less than 0.94 gram per cubic centimeter), and 5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VIII described in table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in table 2 of § 176.170(c) of this chapter and with food types III, IV–A, V, VII–A, and IX described in table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in table 2 of § 176.170(c) of this chapter. |
| 2,2′-Oxamidobis[ethyl 3-(3,5-di-n-ert-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1), | For use only:  
1. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter.  
2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, and 1.3.  
3. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0 that contact food Types I, II, IV–B, VI, VII–B and VIII described in table 1 of § 176.170(c) of this chapter.  
4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0 that contact food Types III, IV–A, V, VII–A, and IX described in table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with items 3.1 and 3.2 where the majority of polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight.  
5. At levels not to exceed 0.1 percent by weight of olefin polymers complying with item 3.4 of § 177.1520(c) of this chapter, that contact food Types III, VII–A, and IX described in table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with item 3.4 where the majority of the polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight. |
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentaerythritol and its stearate ester ..................................</td>
<td>For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with §177.1980 of this chapter. Provided. The total amount of pentaerythritol and/or pentaerythritol stearate (calculated as free pentaerythritol) does not exceed 0.4 percent by weight of such polymers.</td>
</tr>
<tr>
<td>N-Phenylenediamine reaction products with 2,4,4-trimethylpentenes (CAS Reg. No. 68411–46–1)</td>
<td>For use at levels not to exceed 0.5 percent by weight of pressure-sensitive adhesives complying with §175.125 of this chapter.</td>
</tr>
<tr>
<td>Phosphoric acid triesters with triethylene glycol (CAS Reg. No. 64502–13–2)</td>
<td>At levels not to exceed 0.1 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter, such that the polymers contact foods only of Type VI–B described in table 1 of §176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>
| Phosphorous acid, cyclic butyl/ethyl propenol, 2,4,6-tri-tert-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3) | For use only:  
   1. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, or 2.3 (where the density of these polymers is not less than 0.94 gram per cubic centimeter), and items 3.1 or 3.2, provided that the finished polymer contacts foods of types I, II, and VI–B as described in table 1 of §176.170(c) of this chapter.  
   2. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, that contact food of types III, IV, V, VI–A, VI–C, VII, VIII, and IX as described in table 1 of §176.170(c) of this chapter, only under conditions of use C, D, E, F, G, and H as described in table 2 of §176.170(c) of this chapter.  
   3. At levels not to exceed 0.1 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1a, 3.1b, 3.2a, or 3.2b, having a density less than 0.94 grams per cubic centimeter, in contact with food only of types III, IV, V, VI–A, VI–C, VII, VIII, and IX under conditions of use B, C, D, E, F, G, and H as described in tables 1 and 2 of §176.170(c) of this chapter; provided that the food-contact surface does not exceed 0.003 inch (0.076 mm) in thickness.  
   4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 3.1b, 3.1(c), 3.2(a) or 3.2(b), having a density not less than 0.94 grams per cubic centimeter, in contact with foods only of types III, IV, V, VI–A, VI–C, VII, VIII, and IX identified in Table 1 of §176.170(c) of this chapter, and under conditions of use B through H as described in Table 2 of §176.170(c) of this chapter; provided that the food-contact surface does not exceed 0.003 inch (0.076 mm) in thickness. For use only at levels not to exceed 0.10 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, or 3.2, and limited to use in contact with food only under conditions of use B, C, D, E, F, G, and H as described in table 2 of §176.170(c) of this chapter. Olefin polymers that contain more than 50 weight-percent of polymer units derived from ethylene shall have a density equal to or greater than 0.94 gram per cubic centimeter. |
| Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-tert-butyl-4-methylphenyl) ester (CAS Reg. No. 80693–00–1) | For use only:  
   1. At levels not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers complying with §177.1520 of this chapter, for use with all food types described in table 1 of §176.170(c) of this chapter only under conditions of use B through H described in table 2 of §176.170(c) of this chapter.  
   2. At levels not to exceed 0.05 percent by weight of polymers complying with §177.1520(c) of this chapter, item 3.1 or 3.2, and with a maximum thickness of 100 micrometers (0.004 inch) for use with all food types under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter. |
### Substances Limitations

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-tert-butylpheny]ester (CAS Reg. No. 26741–53–7)</td>
<td>For use only: 1. At levels not to exceed 0.06 percent by weight in polyvinyl chloride and/or vinyl chloride copolymers that comply with §§177.1950, 177.1960, 177.1970, or 177.1980 of this chapter for use with all food types described in table 1 of §176.170(c) of this chapter, except those containing more than 15 percent alcohol, under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter. 2. At levels not to exceed 0.25 percent by weight of polycarbonate resins that comply with §177.1580 of this chapter for use with all food types described in table 1 of §176.170(c) of this chapter, except those containing more than 15 percent alcohol, under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>
### § 178.2010

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium bromide and either cupric acetate or cupric carbonate.</td>
<td>For use at levels not exceeding 0.18 percent potassium bromide and 0.005 percent copper as cupric acetate or cupric carbonate by weight of nylon 66 resins complying with §177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250 °F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.</td>
</tr>
<tr>
<td>1,3-propanediamine, N,N′-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine (CAS Reg. No. 136504-96-6).</td>
<td>For use only: 1. At levels not to exceed 0.3 percent by weight of polypropylene complying with §177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 2. At levels not to exceed 0.2 percent by weight of olefin polymers having a density greater than or equal to 0.94 grams per cubic centimeter and complying with §177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, and 3.2. 3. At levels not to exceed 0.3 percent by weight of olefin polymers having a density less than 0.94 grams per cubic centimeter and complying with §177.1520(c) of this chapter, and when used in contact with fatty foods of Types III, IV–A, V, VII–A, and IX as described in Table 1 of §176.170(c) of this chapter, the finished articles are to have a volume of at least 18.9 liters (5 gallons). For use only at levels not to exceed 0.6 percent by weight of rubber articles for repeated use complying with §177.2600 of this chapter.</td>
</tr>
<tr>
<td>N,N′-1,3-Propanediylbis (3,5-di-tert-butyl-4-hydroxyhydrocinnamamide) (CAS Reg. No. 69851-61-2).</td>
<td>For use only as an ultraviolet (UV) stabilizer only at levels not to exceed 0.33 percent by weight of polypropylene complying with §177.1520(c) of this chapter, items 1.1, 1.1b, 1.2, and 1.3, under conditions of use D, E, F, and G, as described in Table 2 of §176.170 of this chapter. For use only at levels not to exceed 0.5 percent by weight of vinyl chloride homopolymers modified in accordance with §178.3790(b)(1). The finished polymers may be used in contact with food containing up to 50 percent alcohol under conditions of use B through H described in table 2 of §176.170(c) of this chapter. For use only in adhesives complying with §175.105 of this chapter and in rubber articles intended for repeated use complying with §177.2600 of this chapter.</td>
</tr>
<tr>
<td>Siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propynoxy)piperidine (CAS Reg. No. 182635-99-0).</td>
<td>For use only at levels not to exceed 0.15 percent by weight of polycarbonate complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1c, 3.2a, and 3.2b. The finished polymers may only be used in contact with food of Types II, IV–B, VI–B, and VIII as described in table 1 of §176.170(c) of this chapter under conditions of use B through H as described in table 2 of §176.170(c) of this chapter, and with food of Types III, IV–A, V, VI–A, VI–B, VII–A, VII–A, and IX as described in table 1 of §176.170(c) of this chapter under conditions of use C through G as described in table 2 of §176.170(c) of this chapter. For use only at levels not to exceed 0.075 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, or 2.3: Provided, That the density of the olefin polymers complying with items 2.1, 2.2, or 2.3 is not less than 0.94 gram per cubic centimeter: And further provided, That the finished polymers contact food only of Types I, II, IV–B, VI–A, VI–B, VII–B, and VIII described in table 1, of §176.170(c) of this chapter, under conditions of use B through H described in table 2 of §176.170(c) of this chapter and food only of Types III, IV–A, V, VI–C, VII–A, and IX described in table 1 of §176.170(c) of this chapter, under conditions of use C through G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>
Substances Limitations

For use only:
1. At levels not to exceed 0.5 percent by weight of all polymers used as indirect additives in food packaging, except as specified below.
2. At levels not to exceed 0.1 percent by weight of petroleum wax or synthetic petroleum wax complying with §176.170(a)(5) of this chapter.
3. At levels not to exceed 1.0 percent by weight of:
   (a) Pressure sensitive adhesives complying with §175.125 of this chapter.
   (b) Can end cement formulations complying with §175.300(b)(3)(xxvi) of this chapter.
   (c) Petroleum alicyclic hydrocarbon resins complying with §175.320(b)(3) of this chapter, §176.170(b)(2) of this chapter, or their hydrogenated products complying with §176.170(b)(2) of this chapter.
   (d) Resins and resin derivatives used in accordance with parts 175 through 178 of this chapter.
   (e) Terpene resins complying with §175.300(b)(2)(i) of this chapter when such terpene resins are used in accordance with §176.170(b) of this chapter.
   (f) Resins and polymers complying with §176.180 of this chapter.
   (g) Closures with sealing gaskets complying with §177.1210 of this chapter.
   (h) Polyoxymethylene copolymer as provided in §177.2470(b)(1) of this chapter.
   (i) Petroleum hydrocarbon resin complying with §178.3800.
   (j) Reinforced wax complying with §178.3850.

4,4-Thiobis(6-tert-butyl-m-cresol) For use only:
1. As provided in §§175.105 and 177.2600 of this chapter.
2. At levels not to exceed 0.25 percent by weight of polyethylene complying with §177.1520 of this chapter: Provided, That the specific gravity of the polyethylene is not less than 0.926: And further provided, That the finished polyethylene contacts food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI–B, and VIII.

Thiodiethylene bis(3,5-di-tert-butyl-4-
hydroxyhydrocinnamate) (CAS Reg. No. 41464-
35-9).

Thiodipropionic acid
1,3,5-Tris(3,5-di-tert-butyl-4-
hydroxybenzyl) benzene (CAS Reg. No. 1709–
70–2).

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

1, 11-(3, 6, 9-Trioxaundecyl) bis-3-(dodecylthio)
propanoate (CAS Reg. No. 64253–30–1).

1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-s-tri-
azine-2,4,6(1H,3H,5H)-trione (CAS Reg. No.
27676–62–6).

1, 3, 5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-
hydroxybenzyl) benzene (CAS Reg. No. 1709–
70–2).

For use only as provided in §175.300(b)(3)(xxvi) of this chapter at 4.0 parts
per 100 parts rubber.

For use only:
1. At levels not to exceed 0.25 percent by weight of polypropylene complying with §177.1520 of this chapter.
2. In polyethylene complying with §177.1520 of this chapter:
   (a) All levels not to exceed 0.1 weight percent.
   (b) All levels not to exceed 0.5 weight percent in contact with nonfatty food.
3. At levels not to exceed 0.5 percent by weight of ethylene-propylene-5-
ethyldiene-2-norbornene terpolymers complying with §177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
4. At levels not exceeding 0.1 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2, and also containing not less than 85 weight percent of polymer units derived from propylene.
5. At levels not exceeding 0.25 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2, and also containing not less than 85 weight percent of polymer units derived from propylene.
6. At levels not to exceed 0.2 percent by weight of olefin copolymers complying with §177.1520(c)(4) of this chapter. The finished polymers may be used in contact with food under conditions of use A through H described in table 2 of §176.170(c) of this chapter.
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3,5-Tris(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl) hexahydro-s-triazine.</td>
<td>For use only in contact with nonfatty foods:</td>
</tr>
<tr>
<td></td>
<td>1. At levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not to exceed 0.1 percent by weight of polyethylene complying with § 177.1520 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>3. At levels not to exceed 0.5 percent by weight of ethylene-propylene-5-ethylidene-2-norbornene terpolymers complying with § 177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
</tr>
<tr>
<td>1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethyl-benzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione. [CAS Reg. No. 40601–76–1].</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520 of this chapter, under conditions of use A through H described in table 2 of § 176.170(c) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not to exceed 0.1 percent by weight of polystyrene and rubber-modified polystyrene that comply with § 177.1640 of this chapter, provided that the finished polystyrene and rubber-modified polystyrene contact food only under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use E through H.</td>
</tr>
<tr>
<td>Substances</td>
<td>Limitations</td>
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</tr>
<tr>
<td>Tris(2,4-di-tert-butylphenyl)phosphite. (CAS Reg. No. 31570-04-6).</td>
<td>For use only:</td>
</tr>
<tr>
<td>1. At levels not to exceed 0.5 percent by weight of elastomers used in rubber articles complying with §177.2600 of this chapter.</td>
<td>1. At levels not to exceed 0.5 percent by weight of elastomers used in rubber articles complying with §177.2600 of this chapter.</td>
</tr>
<tr>
<td>2. At levels not to exceed 1 percent by weight of nylon resins complying with §177.1500 of this chapter: Provided, that the finished polymer contacts food only under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter.</td>
<td>2. At levels not to exceed 1 percent by weight of nylon resins complying with §177.1500 of this chapter: Provided, that the finished polymer contacts food only under conditions of use E, F, and G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>3. At levels not to exceed 0.3 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.</td>
<td>3. At levels not to exceed 0.3 percent by weight of polycarbonate resins complying with §177.1580 of this chapter.</td>
</tr>
<tr>
<td>4. At levels not to exceed 0.2 percent by weight of polyethylene and rubber-modified polyethylene resins complying with §177.1640 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
<td>4. At levels not to exceed 0.2 percent by weight of polyethylene and rubber-modified polyethylene resins complying with §177.1640 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>5. At levels not to exceed 0.25 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1, 2, 3, or 4.</td>
<td>5. At levels not to exceed 0.25 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 1, 2, 3, or 4.</td>
</tr>
<tr>
<td>6. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, or 1.3.</td>
<td>6. At levels not to exceed 0.2 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 1.2, or 1.3.</td>
</tr>
<tr>
<td>7. At levels not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in Table 2 of §176.170(c) of this chapter.</td>
<td>7. At levels not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>8. At levels not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in Table 2 of §176.170(c) of this chapter.</td>
<td>8. At levels not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>9. At levels not to exceed 0.5 percent by weight of acrylic and modified acrylic plastics, semirigid and rigid, complying with §177.1010 of this chapter.</td>
<td>9. At levels not to exceed 0.5 percent by weight of acrylic and modified acrylic plastics, semirigid and rigid, complying with §177.1010 of this chapter.</td>
</tr>
<tr>
<td>10. At levels not to exceed 0.1 percent by weight of isobutylene polymers complying with §177.1420 of this chapter.</td>
<td>10. At levels not to exceed 0.1 percent by weight of isobutylene polymers complying with §177.1420 of this chapter.</td>
</tr>
<tr>
<td>11. In adhesives complying with §175.105 of this chapter.</td>
<td>11. In adhesives complying with §175.105 of this chapter.</td>
</tr>
<tr>
<td>12. At levels not to exceed 0.5 percent by weight of pressure sensitive adhesives complying with §175.125 of this chapter.</td>
<td>12. At levels not to exceed 0.5 percent by weight of pressure sensitive adhesives complying with §175.125 of this chapter.</td>
</tr>
<tr>
<td>13. At levels not to exceed 0.5 percent by weight of can seal cement formulations complying with §175.300(b)(3)(xxxi) of this chapter.</td>
<td>13. At levels not to exceed 0.5 percent by weight of can seal cement formulations complying with §175.300(b)(3)(xxxi) of this chapter.</td>
</tr>
<tr>
<td>14. At levels not to exceed 0.5 percent by weight of side seam cement formulations complying with §175.300(b)(3)(xxxii) of this chapter.</td>
<td>14. At levels not to exceed 0.5 percent by weight of side seam cement formulations complying with §175.300(b)(3)(xxxii) of this chapter.</td>
</tr>
<tr>
<td>15. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
<td>15. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>16. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
<td>16. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>17. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
<td>17. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with §177.1580 of this chapter: Provided, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>18. At levels not to exceed 0.5 percent by weight of acrylic and modified acrylic plastics, semirigid and rigid, complying with §177.1010 of this chapter.</td>
<td>18. At levels not to exceed 0.5 percent by weight of acrylic and modified acrylic plastics, semirigid and rigid, complying with §177.1010 of this chapter.</td>
</tr>
<tr>
<td>19. At levels not to exceed 0.5 percent by weight of isobutylene polymers complying with §177.1420 of this chapter.</td>
<td>19. At levels not to exceed 0.5 percent by weight of isobutylene polymers complying with §177.1420 of this chapter.</td>
</tr>
<tr>
<td>20. At levels not to exceed 0.5 percent by weight of pressure sensitive adhesives complying with §175.125 of this chapter.</td>
<td>20. At levels not to exceed 0.5 percent by weight of pressure sensitive adhesives complying with §175.125 of this chapter.</td>
</tr>
<tr>
<td>21. At levels not to exceed 0.5 percent by weight of reinforced wax complying with §178.3850.</td>
<td>21. At levels not to exceed 0.5 percent by weight of reinforced wax complying with §178.3850.</td>
</tr>
<tr>
<td>22. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, item 3.3. The finished polymers may be used in contact with food under conditions of use A through H described in table 2 of §176.170(c) of this chapter.</td>
<td>22. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, item 3.3. The finished polymers may be used in contact with food under conditions of use A through H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>23. At levels not to exceed 0.15 percent by weight of poly-1-butene resins and butene/ethylene copolymers complying with §177.1570 of this chapter.</td>
<td>23. At levels not to exceed 0.15 percent by weight of poly-1-butene resins and butene/ethylene copolymers complying with §177.1570 of this chapter.</td>
</tr>
</tbody>
</table>
§ 178.2550 4-Hydroxymethyl-2,6-di-tert-butylphenol.

4-Hydroxymethyl-2,6-di-tert-butylphenol may be safely used as an antioxidant in articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140°–141 °C.

(b) The concentration of the additive and any other permitted antioxidants in the finished food-contact article does not exceed a total of 0.5 milligram per square inch of food-contact surface.

§ 178.2650 Organotin stabilizers in vinyl chloride plastics.

The organotin chemicals identified in paragraph (a) of this section may be safety used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in vinyl chloride homopolymers and copolymers complying with the provisions of §177.1950 or §177.1980 of this chapter and that are identified for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated non-alcoholic beverages), VII, VIII, and IX described in table 1 of §176.170(c) of this chapter, except for the organotin chemical identified in paragraph (a)(3) of this section, which may be used in contact with food of types I through IX at temperatures not exceeding 75 °C (167 °F), and further that the organotin chemicals identified in paragraphs (a) (5) and (6) of this section may be used in contact with food of types I through XIX.
I X at temperatures not exceeding 66 °C (150 °F), conditions of use D through G described in table 2 of §176.170(c) of this chapter, and further that dodecyltin chemicals identified in paragraph (a)(7) of this section which may be used in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of §176.170(c) of this chapter at temperatures not exceeding 71 °C (160 °F), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the organotin chemicals are those listed in paragraphs (a)(1), (2), (3), (4), (5), (6), and (7) of this section.

(1) Di(n-octyl)tin S,S′-bis(isooctylmercaptoacetate) is an octyltin chemical having 15.1 to 16.4 percent by weight of tin (Sn) and having 8.1 to 8.9 percent by weight of mercapto sulfur. It is made from di(n-octyl)tin dichloride or di(n-octyl)tin oxide. The isooctyl radical in the mercaptoacetate is derived from o xo process isooctyl alcohol. Di(n-octyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of di(n-octyl)tin dichloride and not more than 5 percent by weight of tri(n-octyl)tin chloride. Di(n-octyl)tin oxide has an organotin composition that is not less than 95 percent by weight of di(n-octyl)tin oxide and not more than 5 percent by weight of bis[tri(n-octyl)tin] oxide, and/or mono n-octyltin oxide.

(2) Di(n-octyl) tin maleate polymer is an octyltin chemical having the formula \( (\text{C}_9\text{H}_{19})_2\text{Sn}(\text{SCH}_2\text{CO}_2\text{CH}_3)_n \) (where \( n \) is between 2 and 4 inclusive), having 25.2 to 28.6 percent by weight of tin (Sn) and having a saponification number of 225 to 255. It is made from di(n-octyl)tin dichloride or di(n-octyl)tin oxide meeting the specifications prescribed for di(n-octyl) tin dichloride or di(n-octyl) tin oxide in paragraph (a)(1) of this section.

(3) C20–28 A lkyl mercaptoacetates reaction products with dichlorodiocytistannane and trichlorooctylstannane (CAS Reg. No. 83447-69-2) is an organotin chemical mixture having 10.8 to 11.8 percent by weight of tin (Sn) and having 8.0 to 8.6 percent by weight of mercapto sulfur.

It is made from a mixture of di(n-octyl)tin dichloride and (n-octyl)tin trichloride which has an organotin composition that is not less than 95 percent by weight di(n-octyl)tin dichloride/(n-octyl)tin trichloride, and not more than 1.5 percent by weight of tri(n-octyl)tin chloride. The alkyl radical in the mercaptoacetate is derived from a mixture of saturated n-alcohols which has a composition that is not less than 50 percent by weight tetradecyl alcohol, and that is not more than 50 percent by weight total of decyl alcohol and/or dodecyl alcohol, and/or hexadecyl alcohol.

(4) (n-Octyl)tin S,S′′ tris(isooctylmercaptoacetate) is an octyltin chemical having the formula \( \text{n-C}_{10-16}\text{Alkyl mercaptoacetates} \text{Sn}(\text{SCH}_2\text{CO}_2\text{C}_8\text{H}_{17})_3 \) (CAS Reg. No. 26401-86-5) having 13.4 to 14.8 percent by weight of tin (Sn) and having 10.9 to 11.9 percent by weight of mercapto sulfur. It is made from (n-octyl)tin trichloride. The isooctyl radical in the mercaptoacetate is derived from o xo process isooctyl alcohol. The (n-octyl)tin trichloride has an organotin composition that is not less than 95 percent by weight of (n-octyl)tin trichloride and not more than 5 percent by weight of tri(n-octyl)tin chloride. The triestertin chloride content of (n-octyl)tin trichloride shall not exceed 0.02 percent.

(5) Bis(beta-carbobutoxyethyl)tin bis(isooctylmercaptoacetate) (CAS Reg. No. 63397-60-4) is an estetin chemical having 14.0 to 15.0 percent by weight of tin (Sn) and having 7.5 to 8.5 percent by weight of mercapto sulfur. It is made from bis(beta-carbobutoxyethyl)tin dichloride. The isooctyl radical in the mercaptoacetate is derived from o xo process primary o cyclt alcohol. The bis(beta-carbobutoxyethyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of bis(beta-carbobutoxyethyl)tin dichloride and not more than 5 percent by weight of bis(beta-carbobutoxyethyl)tin trichloride. The triestertin chloride content of bis(beta-carbobutoxyethyl)tin dichloride shall not exceed 0.02 percent.

(6) Beta-carbobutoxyethyltin tris(isooctylmercaptoacetate) (CAS Reg. No. 63438-80-2) is an estetin chemical having 13.0 to 14.0 percent by weight of tin (Sn) and having 10.5 to
11.5 percent by weight of mercapto sulfur. It is made from beta-carbobutoxyethyltin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohol. The beta-carbobutoxyethyltin trichloride has an organotin composition that is not less than 95 percent by weight of beta-carbobutoxyethyltin trichloride and not more than 5 percent total of triestertin chloride and diestertin chloride.

(7) The dodecyltin stabilizer is a mixture of 50 to 60 percent by weight of \( n \)-dodecyltin \( S,S',S'' \)-tris(isooctylmercaptoacetate) (CAS Reg. No. 67649-65-4) and 40 to 50 percent by weight of di(\( n \)-dodecyl)tin \( S,S' \)-di(isooctylmercaptoacetate) (CAS Reg. No. 84030-61-5) having 13 to 14 percent by weight of tin (Sn) and having 8 to 9 percent by weight of mercapto sulfur. It is made from a mixture of dodecyltin trichloride and di(dodecyl)tin dichloride which has not more than 0.2 percent by weight of dodecyltin trichloride, not more than 2 percent by weight of dodecylbutyltin dichloride and not more than 3 percent by weight of tri(dodecyl)tin chloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols.

(b) The vinyl chloride plastic containers, film or panels in the finished form in which they are to contact food, shall meet the following limitations:

(1) The finished plastics intended for contact with foods of the types listed in this section shall be extracted with the solvent or solvents characterizing those types of foods as determined from table 2 of §176.170(c) of this chapter at the temperature reflecting the conditions of intended use as determined therein. Additionally, extraction tests for acidic foods shall be included and simulated by 0.1 percent acetic acid at temperatures specified for water in table 2 of §176.170(c) of this chapter. The extraction tests shall cover at least three equilibrium periodic determinations, as follows:

(i) The exposure time for the first determination shall be at least 72 hours for aqueous solvents, and at least 6 hours for heptane. Subsequent determinations shall be at a minimum of 24-hour intervals for aqueous solvents, and 2-hour intervals for heptane. These tests shall yield total octyltin stabilizers not to exceed 5 parts per million as determined by analytical method entitled “Atomic Absorption Spectrophotometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace,” Analytical Chemistry, Vol. 49, p. 1090-1093 (1977), which is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Subsequent determinations for the dodecyltin mixture described in paragraph (a)(7) of this section shall be at a minimum of 24-hour intervals for aqueous solvents and 2-hour intervals for heptane. These tests shall yield di(\( n \)-octyl)tin \( S,S' \)-bis(isooctylmercaptoacetate), or di(\( n \)-octyl)tin maleate polymer, or \((C_{10}-C_{16})\)-alkylmercaptoacetate reaction products with dichlorodioctylstannane and trichlorooctylstannane, or \( n \)-octyltin \( S,S',S'' \)-tris(isooctylmercaptoacetate), tris(isooctylmercaptoacetate) and di(\( n \)-dodecyl)tin bis(isooctylmercaptoacetate) or any combination thereof, not to exceed 0.5 parts per million as determined by an analytical method entitled “Atomic Absorption Spectrophotometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace,” Analytical Chemistry, Vol. 49, pp. 1090-1093 (1977), which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) In lieu of the tests prescribed in paragraph (b)(1) of this section, the finished plastics intended for contact with foods only of Types II, V, VI-A (except malt beverages), and VI-C may be end-tested with food-simulating solvents, under conditions of time and temperature, as specified below, where by such tests shall yield the octyltin...
residues cited in paragraph (b)(1) of this section not in excess of 0.5 ppm:

<table>
<thead>
<tr>
<th>Food-simulating solvent</th>
<th>Time (hours)</th>
<th>Temperature (degrees Fahrenheit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type II ..................</td>
<td>48</td>
<td>135</td>
</tr>
<tr>
<td>Type V ...................</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>Type VI±A ..............</td>
<td>24</td>
<td>120</td>
</tr>
<tr>
<td>Type VI±C ..............</td>
<td>24</td>
<td>120</td>
</tr>
</tbody>
</table>


Subpart D—Certain Adjuvants and Production Aids

§ 178.3010 Adjuvant substances used in the manufacture of foamed plastics.

The following substances may be safely used as adjuvants in the manufacture of foamed plastics intended for use in contact with food, subject to any prescribed limitations:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azodicarbonamide</td>
<td>For use as a blowing agent in polyethylene complying with item 2.1 in §177.1520(c) of this chapter at a level not to exceed 5 percent by weight of finished foamed polyethylene.</td>
</tr>
<tr>
<td>1,1-Difluoroethane (CAS Reg. No. 75-37-6)</td>
<td>For use as a blowing agent in polystyrene.</td>
</tr>
<tr>
<td>Isopentane ...........</td>
<td>For use as a blowing agent in polystyrene.</td>
</tr>
<tr>
<td>n-Pentane ............</td>
<td>For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.3 percent by weight of finished foamed polystyrene intended for use in contact with food only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, VI, and VIII.</td>
</tr>
<tr>
<td>1,1,2,2-Tetrachloroethylene</td>
<td>Do.</td>
</tr>
</tbody>
</table>


§ 178.3120 Animal glue.

Animal glue may be safely used as a component 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) Animal glue consists of the proteinaceous extractives obtained from hides, bones, and other collagen-rich substances of animal origin (excluding diseased or rotted animals), to which may be added other optional adjuvant substances required in its production or added to impart desired properties.

(b) The quantity of any substance employed in the production of animal glue does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitation further provided.

(c) Any substance employed in the production of animal glue and which 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) Optional adjuvant substances employed in the production of animal glue include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in animal glue and used in accordance with such sanction or approval.

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

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alum (double sulfate of aluminum and ammonium, potassium, or sodium)</td>
<td>For use as preservative only.</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol(p-chlorometacresol)</td>
<td>For use only in glue used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paper board.</td>
</tr>
<tr>
<td>3,5-Dimethyl-1,3,5-Hexatriahydrothiadiazine-2-thione</td>
<td>For use as preservative only.</td>
</tr>
<tr>
<td>Disodium cyanodithioimidocarbonate</td>
<td>As provided in §176.210 of this chapter.</td>
</tr>
</tbody>
</table>

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List of substances | Limitations
--- | ---
Ethanolamine. | For use as a preservative only.
Ethylenediamine. | Do.
Potassium N-methylthiocarbamate | As provided in §178.3870.
Potassium pentachlorophenate | Do.
Rosins and rosin derivatives | Do.
Sodium chlorate. | Do.
Sodium dodecylbenzenesulfonate. | Do.
Sodium 2-mercaptopbenothiazole | Do.
Sodium pentachlorophenate | Do.
Sodium o-phenylphenate | Do.
Zinc dimethylthiocarbamate | Do.
Zinc 2-mercaptothiazole | Do.

(e) The conditions of use are as follows:

1. The use of animal glue in any substance or article that is the subject of a regulation in this subpart conforms with any specifications or limitations prescribed by such regulation for the finished form of the substance or article.

2. It is used as an adhesive or component of an adhesive in accordance with the provisions of §175.105 of this chapter.

3. If used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paperboard.

4. It is used as a protective colloid in resinous and polymeric emulsion coatings.

§178.3125 Anticorrosive agents.

The substances listed in this section may be used as anticorrosive agents in food-contact materials subject to the provisions of this section:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc hydroxy phosphate (CAS Reg. No. 55799-16-1).</td>
<td>For use only as a component of resinous and polymeric food-contact coatings intended for repeated use in contact with dry foods.</td>
</tr>
</tbody>
</table>

[50 FR 21835, May 29, 1985]

§178.3130 Antistatic and/or antifogging agents in food-packaging materials.

The substances listed in paragraph (b) of this section may be safely used as antistatic and/or antifogging agents in food-packaging materials, subject to the provisions of this section:

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

(b) List of substances:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| N-Acyl sarcosines where the acyl group is lauroyl, oleoyl, or derived from the combined fatty acids of coconut oil. | For use only:
1. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of polyolefin film used for packaging meat, fresh fruits, and fresh vegetables. The average thickness of such polyolefin film shall not exceed 0.003 inch.
2. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of ethylene-vinyl acetate copolymer film complying with §177.1350 of this chapter and used for packaging meat, fresh fruits, fresh vegetables, and dry food of Type VIII described in table 1 of §176.170(c) of this chapter. The average thickness of such ethylene-vinyl acetate copolymer film shall not exceed 0.003 inch when used for packaging meat, fresh fruits, and fresh vegetables. |
3. As antistatic and/or antifogging agent at levels not to exceed a total of 0.2 pct by weight in polyolefin film not exceeding 0.001 inch thickness. |
| Alpha-(Carboxymethyl)-omega-(tetradecyloxy)polyoxyethylene) | For use only as an antistatic and/or antifogging agent at levels not to exceed 0.2 pct by weight in polyolefin film not exceeding 0.001 inch thickness. |
### Food and Drug Administration, HHS

#### § 178.3130

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Alkyl mono- and disulfonic acids, sodium salts (produced from \(n\)-alkanes in the range of \(C_{10} - C_{18}\) with not less than 50 percent \(C_{14} - C_{16}\)). | For use only:  
1. As antistatic agents at levels not to exceed 0.1 percent by weight of polyolefin films that comply with §177.1520 of this chapter: Provided, that the finished olefin polymers contact foods of Types I, II, III, IV, V, VI, VII–A, VII–B, VIII, and IX described 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.  
2. As antistatic agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with §177.1640 of this chapter under conditions of use B through H described in table 2 of §176.170(c) of this chapter. |
| Aluminum Borate (\((9\text{Al}_2\text{O}_3\cdot 2\text{B}_2\text{O}_3)\), CAS Reg. No. 11121–16–7) produced by reaction between aluminum oxide and/or aluminum hydroxide with boric acid and/or metaboric acid at temperatures in excess of 1000 °C. | For use only:  
1. At levels not to exceed 1 percent by weight of polypropylene films complying with §177.1520(c) of this chapter, item 1.1, of polyethylene films complying with §177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with §177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of §176.170(c) of this chapter, under conditions of use A through H as described in Table 2 of §176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch.  
2. At levels not to exceed 2 percent by weight of polypropylene films complying with §177.1520(c) of this chapter, item 1.1, of polyethylene films complying with §177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with §177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of §176.170(c) of this chapter under conditions of use B through H as described in Table 2 of §176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch. |
| N,N-Bis(2-hydroxyethyl)alkyl(C\(_{12} - C_{18}\))amine | For use only as an antistatic agent at levels not to exceed 0.1 percent by weight of polyolefin food-contact films.  
For use only:  
1. As an antistatic agent at levels not to exceed 0.2 percent by weight in molded or extruded high-density polyethylene having a density \(\geq 0.95\) g/cm\(^3\) and polypropylene containers that contact food only of the types identified in §176.170(c) of this chapter, Table 1, under types I, VI–B, VII–B, and VIII, under the conditions of use E through G described in Table 2 of §176.170(c) of this chapter, provided such foods have a pH above 5.6.  
2. As an antistatic agent at levels not to exceed 0.1 percent by weight in molded or extruded polypropylene homopolymers and copolymers that contact food only of the types identified in §176.170(c) of this chapter, Table 1, under Types II, III, IV, V, VII–A, and IX, under the conditions of use C through G described in Table 2 of §176.170(c) of this chapter. |
| N,N-Bis(2-hydroxyethyl)(C\(_{13} - C_{15}\))amine (CAS Reg. No. 70955–14–5) | }
N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups \((C_{14}-C_{18})\) are derived from tallow.

N,N-Bis(2-hydroxyethyl)dodecanamide produced when dithanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free dithanolamine; and contains no more than 0.5 percent by weight of N,N-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method.

N,N-Bis(2-hydroxyethyl) dodecanamide produced when dithanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free dithanolamine; and contains no more than 0.5 percent by weight of N,N-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method.

N,N-Bis(2-hydroxyethyl)octadecylamine, Chemical Abstracts Service Registry No. 10213-78-2, N-(2-hydroxyethyl)-N-octadeclglycine (monosodium salt), Chemical Abstracts Service Registry No. 66810-88-6, and N,N-Bis(2-hydroxyethyl)-N(carboxymethyl)octadecanaminium hydroxide (inner salt), Chemical Abstracts Service Registry No. 24170-14-7, as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with sodium monochloroacetate and sodium hydroxide, such that the final product has: A nitrogen content of 3.3–3.8 percent; a melting point of 42–50 °C; and a pH of 10.0–11.5 in a 1 percent by weight aqueous solution.

ρ-n-Dodecanol-omega-hydroxypropyl (oxyethylene) produced by the condensation of 1 mole of \(n\)-dodecanol with an average of 9.5 moles of ethylene oxide to form a condensate having a hydroxyl content of 2.7 to 2.9 pct and having a cloud point of 80 °C to 92 °C in 1 pct by weight aqueous solution.

Glycerol ester mixtures of ricinoleic acid, containing not more than 50 percent monoricinoleate, 45 pct diricinoleate, 10 pctl tricinoleate, and 3.3 pctl free glycerine.

\(N\)-Methacryloyloxyethyl-\(N\)-Ndimethylammonium-\(\alpha\)-N-methyl carboxylate chloride sodium salt, octadecyl methacrylate, ethyl methacrylate, cyclohexyl methacrylate, N-vinyl-2-pyrolidone copolymer (CAS Reg. No. 66822-60-4).

List of substances

| N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups \((C_{14}-C_{18})\) are derived from tallow. |
| N,N-Bis(2-hydroxyethyl)dodecanamide produced when dithanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free dithanolamine; and contains no more than 0.5 percent by weight of N,N-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method. |
| N,N-Bis(2-hydroxyethyl) dodecanamide produced when dithanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free dithanolamine; and contains no more than 0.5 percent by weight of N,N-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method. |
| N,N-Bis(2-hydroxyethyl)octadecylamine, Chemical Abstracts Service Registry No. 10213-78-2, N-(2-hydroxyethyl)-N-octadeclglycine (monosodium salt), Chemical Abstracts Service Registry No. 66810-88-6, and N,N-Bis(2-hydroxyethyl)-N(carboxymethyl)octadecanaminium hydroxide (inner salt), Chemical Abstracts Service Registry No. 24170-14-7, as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with sodium monochloroacetate and sodium hydroxide, such that the final product has: A nitrogen content of 3.3–3.8 percent; a melting point of 42–50 °C; and a pH of 10.0–11.5 in a 1 percent by weight aqueous solution. |
| ρ-n-Dodecanol-omega-hydroxypropyl (oxyethylene) produced by the condensation of 1 mole of \(n\)-dodecanol with an average of 9.5 moles of ethylene oxide to form a condensate having a hydroxyl content of 2.7 to 2.9 pct and having a cloud point of 80 °C to 92 °C in 1 pct by weight aqueous solution. |
| Glycerol ester mixtures of ricinoleic acid, containing not more than 50 percent monoricinoleate, 45 pct diricinoleate, 10 pctl tricinoleate, and 3.3 pctl free glycerine. |
| \(N\)-Methacryloyloxyethyl-\(N\)-Ndimethylammonium-\(\alpha\)-N-methyl carboxylate chloride sodium salt, octadecyl methacrylate, ethyl methacrylate, cyclohexyl methacrylate, N-vinyl-2-pyrolidone copolymer (CAS Reg. No. 66822-60-4). |

Limitations

For use only:

1. As an antistatic agent at levels not to exceed 0.15 pct by weight in molded or extruded polyethylene containers that contact food only of the types identified in §176.170(c) of this chapter, and under conditions of use B through H described in table 2 of §176.170(c) of this chapter provided such foods have a pH above 5.0.

2. As an antistatic agent at levels not to exceed 0.10 mg. per square inch of food-contact surface in vinylidene chloride copolymer coatings complying with §175.300, §177.1600, or §177.1630 of this chapter, provided that such coatings contact food only of the types identified in §176.170(c) of this chapter, table 1, under Types I, IV, VII, VIII, and IX under the conditions of use E through G described in table 2 of §176.170(c) of this chapter. The finished copolymers shall contain at least 70 weight pct of polymer units derived from vinylidene chloride; and shall contain not more than 5 weight pct of total polymer units derived from acrylicamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.

For use only as an antistatic agent at levels not to exceed 0.05 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in table 1 of §176.170(c) of this chapter.

For use only as an antistatic agent at levels not to exceed 0.2 percent by weight in polypropylene films complying with §177.1520 of this chapter, such as those used in contact with foods of Types I, II, III, IV, V, VI-B, VII-B, VII, VIII, and IX described in table 1 of §176.170(c) of this chapter, and under conditions of use E through H described in table 2 of §176.170(c) of this chapter. The average thickness of such polypropylene film shall not exceed 0.001 inches (30 micrometers).

For use only as an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in table 1 of §176.170(c) of this chapter.

For use only as an antistatic agent at levels not to exceed 0.2 percent by weight in polypropylene films complying with §177.1520 of this chapter, and used in contact with food of Types I, II, III, IV, V, VI-B, VII-B, VII, VIII, and IX described in table 1 of §176.170(c) of this chapter, and under conditions of use B through H described in table 2 of §176.170(c) of this chapter. The average thickness of such polypropylene film shall not exceed 0.002 inch.

For use only as an antistatic agent at levels not to exceed 0.45 percent by weight in polypropylene films complying with §177.1520 of this chapter, and used in contact with foods of Types I, II, III, IV, V, VI-B, VII, VIII, and IX described in table 1 of §176.170(c) of this chapter, and used in contact with foods of Types I, IV-B, VI-B, VII-B, VII, VIII, under the conditions of use E through H described in table 2 of §176.170(c) of this chapter. The average thickness of such polypropylene film shall not exceed 0.0025 inch.

For use only as an antistatic agent at levels not to exceed 0.2 pct by weight in low-density polyethylene film having an average thickness not exceeding 0.005 inch.

As an antifoaming agent at levels not exceeding 1.5 pct by weight of permitted plasticized vinyl chloride homopolymer copolymers.

For use only as an antistatic agent at levels not to exceed 0.2 percent by weight of polyolefin films that contact foods under the conditions of use B through H described in table 2 of §176.170(c) of this chapter. The average thickness of such polyolefin film shall not exceed 0.02 centimeter (0.008 inch).
Octadecanoic acid 2-[2-hydroxyethyl]octadecylaminoethyl ester (CAS Reg. No. 52497-24-2), (octadecyliminodiacetyl) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2), as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with octadecanoic acid, such that the final product has: a maximum acid value of 5 mg KOH/g and total amine value of 86±6 mg KOH/g as determined by a method entitled "Total Amine Value," which is incorporated by reference. Copies of the method 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. For use only as an antistatic agent at levels such that the product of film thickness in microns times the weight percent additive does not exceed 16, in polypropylene films complying with §177.1520(c)(1) of this chapter, and used for packaging food (except for food containing more than 8 percent alcohol) under conditions of use B through H described in table 2 of §176.170(c) of this chapter.

**§ 178.3280 Castor oil, hydrogenated.**

Hydrogenated castor oil may be safely used in the manufacture of articles or components of articles intended for use in contact with 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.

(b) The additive is used as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. As a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles authorized for food-contact use.</td>
<td>For use only at levels not to exceed 4 percent by weight of vinyl chloride polymers. Complying with §177.1200 of this chapter.</td>
</tr>
<tr>
<td>2. As a component of cellophane.</td>
<td></td>
</tr>
<tr>
<td>3. As a component of resinous and polymeric coatings.</td>
<td></td>
</tr>
<tr>
<td>4. As a component of paper and paperboard in contact with aqueous and fatty food.</td>
<td></td>
</tr>
<tr>
<td>5. As a component of closures with sealing gaskets for food containers.</td>
<td></td>
</tr>
<tr>
<td>6. As a component of cross-linked polyester resins.</td>
<td></td>
</tr>
<tr>
<td>7. As a component of olefin polymers complying with §177.1520 of this chapter.</td>
<td>Complying with §177.1210 of this chapter. Complying with §177.2420 of this chapter. For use only at levels not to exceed 2 percent by weight of the polymer.</td>
</tr>
</tbody>
</table>


**§ 178.3290 Chromic chloride complexes.**

Myristo chromic chloride complex and stearato chromic chloride complex may be safely used as release agents in the closure area of packaging containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

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

(b) The packaging container which has its closure area treated with the release agent shall have a capacity of not less than 120 grams of food per square inch of such treated closure area.

[42 FR 14609, Mar. 15, 1977, as amended at 55 FR 8914, Mar. 9, 1990]

**§ 178.3295 Clarifying agents for polymers.**

Clarifying agents may be safely used in polymers that are articles or components of articles intended for use in contact with food, subject to the provisions of this section:
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum, hydroxybis[2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxidato]- (CAS Reg. No. 151841–65–5).</td>
<td>For use only as a clarifying agent at levels not to exceed 0.25 percent by weight of polypropylene and polypropylene copolymers complying with §177.1520(c) of this chapter, items 1.1, 3.1, or 3.2. The finished polymers contact food only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of §176.170(c) of this chapter, under conditions of use B through H described in Table 2 of §176.170(c) of this chapter, or foods only of types III, IV-A, V, VI-A, VI-C, VII-A, and IX as identified in Table 1 of §176.170(c) of this chapter, under conditions of use C through G described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Bis(p-ethylbenzylidene) sorbitol (CAS Reg. No. 79072–96–1)</td>
<td>For use only as a clarifying agent at a level not to exceed 0.35 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.2a, or 3.2b, where the copolymers complying with items 3.1a, 3.2a, or 3.2b contain not less than 85 weight percent of polymer units derived from propylene.</td>
</tr>
<tr>
<td>Di(p-tolylidene) sorbitol (CAS Reg. No. 54686–97–4)</td>
<td>For use only as a clarifying agent at a level not to exceed 0.32 percent by weight in propylene homopolymer complying with §177.1520(c) of this chapter, item 3.1 (containing at least 85 weight percent of polymer units derived from propylene), in contact with all food types under conditions of use C through G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Dibenzylidene sorbitol (CAS Reg. No. 32047–67–9) formed by the condensation of two moles of benzaldehyde with one mole of sorbitol, such that the final product has a minimum content of 95 percent dibenzylidene sorbitol.</td>
<td>For use only as a clarifying agent for olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 3.1, and 3.2 of this chapter under conditions of use C, D, E, F, and G, described in table 2 of §176.170(c) of this chapter at a level not exceeding 0.25 percent by weight of the polymer.</td>
</tr>
<tr>
<td>Dimethylbenzylidene sorbitol (CAS Reg. No. 135861–56–2)</td>
<td>For use only as a clarifying agent at a level not to exceed 0.4 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene. The finished polymers shall be used in contact with food under conditions of use A through H described in table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Polyvinylcyclohexene (CAS Reg. No. 25498–06–0)</td>
<td>For use only as a clarifying agent for polypropylene complying with §177.1520(c) of this chapter, item 1.1., and in propylene containing copolymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2, at a level not exceeding 0.1 percent by weight of the polyolefin.</td>
</tr>
<tr>
<td>Sodium di(p-tert-butylphenyl)phosphate (CAS Reg. No. 10491–31–3).</td>
<td>For use only as a clarifying agent at a level not exceeding 0.35 parts per hundred of the resin in olefin polymers complying with §177.1520(c) of this chapter, items 3.1 and 3.2, at a level not exceeding 0.1 percent by weight of the polyolefin. For use only as a clarifying agent at a level not exceeding 0.35 percent by weight of the polymer in contact with food under conditions of use C through G described in table 2 of §176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>
§ 178.3297 Colorants for polymers.

The substances listed in paragraph (e) of this section may be safely used as colorants 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 and definitions set forth in this section:

(a) The term colorant means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term "colorant" includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Center for Food Safety and Applied Nutrition, (HFS-200) Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(d) Color additives and their lakes listed for direct use in foods, under the

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For use only:

1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of §176.170(c) of this chapter and limited to conditions of use B through H, described in Table 2 of §176.170(c), or foods of all types, limited to conditions of use C through H described in Table 2 of §176.170(c).

2. As a clarifying agent at levels not exceeding 0.10 percent by weight of polypropylene complying with §177.1520(c) of this chapter, items 1.1(a) or 1.1(b) and of olefin polymers complying with §177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b) (where the copolymers contain not less than 85 weight percent of the polymer units derived from polypropylene.) The finished polymers shall be used in contact with foods only under conditions of use A through H described in Table 2 of §176.170(c) of this chapter.

3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with §177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV-B, VI-B, and VII-B as identified in Table 1 of §176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of §176.170(c) of this chapter, or foods of types III, IV-A, V, VI-C, and VII-A as identified in Table 1 of §176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of §176.170(c) of this chapter.
provisions of the color additive regulations in parts 73, 74, 81, and 82 of this chapter, may also be used as colorants for food-contact polymers.

(e) List of substances:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact foods only under conditions of use B through H described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Aluminum hydrate</td>
<td></td>
</tr>
<tr>
<td>Aluminum and potassium silicate (mica)</td>
<td></td>
</tr>
<tr>
<td>Aluminum mono-, di-, and tristearate</td>
<td></td>
</tr>
<tr>
<td>Aluminum silicate (China clay)</td>
<td></td>
</tr>
<tr>
<td>4-[5-{4-[Aminocarbonyl]phenyl] amino[carbonyl]2-methoxyphenyl]azo-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-2-naphthalamine-carboxamide (C.I. Pigment Red 187, CAS Reg. No. 59487-93-9).</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact foods only under conditions of use B through H described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>4-[Aminocarbonyl]phenyl]-4-[1-{2,3-dihydro-2-oxo-1H-benzenimidazol-5-ylamino}carbonyl]-2-oxopropiyl]azo]benzamide (C.I. Pigment Yellow 181, CAS Reg. No. 74441-05-7).</td>
<td>For use at levels not to exceed 1% by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Anthra(2,1,9-def:(6,5,10-d′e′f)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29, CAS Reg. No. 81-33-4).</td>
<td>For use at levels not to exceed 1% by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Barium sulfate</td>
<td>For use at levels not to exceed 0.0004 percent by weight of polyethylene phthalate polymers complying with §177.1630 of this chapter.</td>
</tr>
<tr>
<td>Bentonite</td>
<td>For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in Table 2 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Bentonite, modified with 3-dimethyldecylammonium ion.</td>
<td>For use only in the textile fibers specified in §177.2800 of this chapter. Do.</td>
</tr>
</tbody>
</table>
Cobalt aluminate .............................................................. For use only:
1. In resins and polymeric coatings complying with §175.300 of this chapter.
2. Melamine-formaldehyde resins in molded articles complying with §176.160 of this chapter.
3. Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydin epoxy resins complying with §175.380 of this chapter.
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.
6. At levels not to exceed 5 percent by weight of all polymers except those listed under limitations 1 through 5 of this item. The finished articles are to contact food under conditions of use A through H described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H as described in table 2 of §176.170(c) of this chapter.


D&C Red No. 7 and its lakes.

Diatomaceous earth.

4,4′-Diamino-[1,1′-biphenyl]-9,9′,10,10′-tetronate (CAS Reg. No. 4051–63–2).

For use only:
1. At levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H described in table 2 of §176.170(c) of this chapter.
2. At levels not to exceed 10.0 percent by weight of polymers.

For use at levels not to exceed 5 percent by weight of polymers.

For use at levels not to exceed 1 percent by weight of polymers.

For use at levels not to exceed 1.0 percent by weight of polymers.

For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H as described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 1 percent by weight of polymers.

For use at levels not to exceed 0.025 percent by weight of polymer. The finished articles are to contact food only under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 0.025 percent by weight of polymer. The finished articles are to contact food only under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 0.025 percent by weight of polymer. The finished articles are to contact food only under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 0.025 percent by weight of polymer. The finished articles are to contact food only under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

For use at levels not to exceed 0.025 percent by weight of polymer. The finished articles are to contact food only under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

For use as an optical brightener for all polymers at a level not to exceed 0.025 percent by weight of polymer. The finished polymer shall contact foods only of the types identified in table 1 of §176.170(c) of this chapter, under categories I, II, IV–B, VI–A, VI–B, VII–B, and VIII at temperatures not to exceed 275 °F.
### § 178.3297

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-purity furnace black (CAS Reg. No. 1333-86-4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled “Determination of PAH Content of Carbon Black,” dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 200 C St. SW., rm. 3337, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.</td>
<td>For use at levels not to exceed 2.5 percent by weight of the polymer.</td>
</tr>
<tr>
<td>Kaolin-modified, produced by treating kaolin with a reaction product of isopropyl titanate and oleic acid in which 1 mole of isopropyl titanate is reacted with 1 to 2 moles of oleic acid. The reaction product will not exceed 8 percent of the modified kaolin. The oleic acid used shall meet the requirements specified in § 172.860 of this chapter.</td>
<td>For use only in olefin polymers complying with § 177.1520 of this chapter at levels not to exceed 40 percent by weight of olefin polymer.</td>
</tr>
<tr>
<td>Magnesium oxide.</td>
<td>For use as an optical brightener only at levels not to exceed 0.05 percent by weight of rigid and semirigid polyvinyl chloride and not to exceed 0.03 percent by weight in all other polymers. The finished food-contact articles shall be used only under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Magnesium silicate (talc).</td>
<td>For use as an optical brightener only in: 1. Olefin polymers complying with § 177.1520 of this chapter at levels such that the product of concentration of the optical brightener (expressed in parts per million by weight of the olefin polymer) multiplied by the thickness of the olefin polymer (expressed in thousandths of an inch and limited to no more than 0.400 inch) shall not exceed 500; provided that the level of the brightener shall not exceed 20 parts per million by weight of the olefin polymer, and further that the olefin polymers shall comply with specifications for items 1.1, 2.1, 3.1, 3.3, and 4 of § 177.1520(c) of this chapter. The polymer may be used under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use E, F, and G. 2. Polyethylene terephthalate specified in § 177.2800(d)(5)(i) of this chapter at a level not to exceed 0.035 percent by weight of the finished fibers.</td>
</tr>
<tr>
<td>Nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53, CAS Reg. No. 8007-18-9).</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV-A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use E, F, and G.</td>
</tr>
<tr>
<td>Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8). Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)</td>
<td>For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.</td>
</tr>
<tr>
<td>Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)</td>
<td>For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in table 2, § 176.170(c) of this chapter.</td>
</tr>
<tr>
<td>Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8). Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)</td>
<td>For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.</td>
</tr>
<tr>
<td>Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8). Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)</td>
<td>For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.</td>
</tr>
<tr>
<td>Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8). Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)</td>
<td>For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.</td>
</tr>
<tr>
<td>Nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53, CAS Reg. No. 8007-18-9).</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV-A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use E, F, and G.</td>
</tr>
<tr>
<td>Nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53, CAS Reg. No. 8007-18-9).</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV-A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use E, F, and G.</td>
</tr>
<tr>
<td>Nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53, CAS Reg. No. 8007-18-9).</td>
<td>For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV-A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use E, F, and G.</td>
</tr>
</tbody>
</table>

For use only at levels not to exceed 2.5 percent by weight of the polymer.
### Food and Drug Administration, HHS

#### § 178.3300

**Substances**  
**Limitations**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,5,6,7-Tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-1H-isooindole-1,3(2H)-dione (C. I. Pigment Yellow 138, CAS Reg. No.30125-47-4).</td>
<td>For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use C through H, as described in table 2 of §176.170(c) of this chapter; provided further that the finished articles shall not be filled at temperatures exceeding 158 °F (70 °C).</td>
</tr>
</tbody>
</table>
| 2,2′-(2,5-Thiophenediyl)-bis(5-tert-butylbenzoxazole) (CAS Reg. No. 7128-64-5). | For use as an optical brightener:  
1. In all polymers at levels not to exceed 0.015 percent by weight of the polymer. The finished articles are to contact food only under conditions of use A through H described in table 2 of §176.170(c) of this chapter.  
2. In all polymers at levels not to exceed 0.05 percent by weight of the polymer. The finished articles shall contact foods only of the types identified in table 1 of §176.170(c) of this chapter, under Categories I, II, IV±B, VI±A, VI±B, VI±C, VII±B, and VIII under conditions of use A through H described in table 2 of §176.170(c) of this chapter.  
3. In adhesives complying with §175.105 of this chapter and in pressure-sensitive adhesives complying with §175.125 of this chapter. |
| Titanium dioxide.                                                        | For use only:  
1. In resinous and polymeric coatings complying with §175.300 of this chapter.  
2. Melamine-formaldehyde resins in molded articles complying with §177.1460 of this chapter.  
3. Xylene-formaldehyde resins condensed with 4-4′-isopropylidene diphenol-epichlorohydrin epoxy resins complying with §175.380 of this chapter.  
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.  
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.  
For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Titanium dioxide-barium sulfate.                                         | As identified in §73.2725 of this chapter.                                  |
| Titanium dioxide-magnesium silicate.                                    | For use only:  
1. In resinous and polymeric coatings complying with §175.300 of this chapter.  
2. Melamine-formaldehyde resins in molded articles complying with §177.1460 of this chapter.  
3. Xylene-formaldehyde resins condensed with 4-4′-isopropylidene diphenol-epichlorohydrin epoxy resins complying with §175.380 of this chapter.  
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.  
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.  
For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Ultramarines                                                             | For use only:  
1. In resinous and polymeric coatings complying with §175.300 of this chapter.  
2. Melamine-formaldehyde resins in molded articles complying with §177.1460 of this chapter.  
3. Xylene-formaldehyde resins condensed with 4-4′-isopropylidene diphenol-epichlorohydrin epoxy resins complying with §175.380 of this chapter.  
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.  
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.  
For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Zinc carbonate                                                           | For use only:  
1. In resinous and polymeric coatings complying with §175.300 of this chapter.  
2. Melamine-formaldehyde resins in molded articles complying with §177.1460 of this chapter.  
3. Xylene-formaldehyde resins condensed with 4-4′-isopropylidene diphenol-epichlorohydrin epoxy resins complying with §175.380 of this chapter.  
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.  
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.  
For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Zinc chromate                                                            | For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Zinc oxide                                                               | For use only:  
1. In resinous and polymeric coatings complying with §175.300 of this chapter.  
2. Melamine-formaldehyde resins in molded articles complying with §177.1460 of this chapter.  
3. Xylene-formaldehyde resins condensed with 4-4′-isopropylidene diphenol-epichlorohydrin epoxy resins complying with §175.380 of this chapter.  
4. Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter.  
5. Urea-formaldehyde resins in molded articles complying with §177.1900 of this chapter.  
For use only in rubber articles for repeated use complying with §177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article. |
| Zinc sulfide                                                             | For use at levels not to exceed 10 percent by weight.                      |


EDITORIAL NOTE: For Federal Register citations affecting §178.3297, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 178.3300 Corrosion inhibitors used for steel or tinplate.

Corrosion inhibitors may be safely used for steel or tinplate intended for use in, or to be fabricated as, food containers or food-processing or handling equipment, subject to the provisions of this section.

(a) The corrosion inhibitors are prepared from substances identified in this section and used subject to the limitations prescribed.

(b) The following corrosion inhibitors or adjuvants are used in amounts not to exceed those reasonably required to accomplish the intended physical or technical effect:

1. Corrosion inhibitors (active ingredients) used in packaging materials for the packaging of steel or tinplate or articles fabricated therefrom:
§ 178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as emulsifiers and/or surface-active agents 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 quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface-active agent 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 conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>α-Alkyl-, α-alkeny-, and α-alkylaryl-omega-hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of α-(2,4,6-trisobutylphenyl)-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of α-(Z)-9-octadecenyl-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and α-alkyl(C&lt;sub&gt;16&lt;/sub&gt;±C&lt;sub&gt;18&lt;/sub&gt;)-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles.</td>
<td>For use only at levels not to exceed 0.5 pct by weight of coatings complying with §175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in §178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.</td>
</tr>
<tr>
<td>n-Alkylbenzenesulfonic acid (alkyl group consisting of not less than 95 percent C&lt;sub&gt;10&lt;/sub&gt; to C&lt;sub&gt;16&lt;/sub&gt;) and its ammonium, calcium, magnesium, potassium, and sodium salts.</td>
<td>For use only: 1. As provided in §176.170 of this chapter. 2. At levels not to exceed 2 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1860 of this chapter. 3. As emulsifiers in vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contains food safe of the Types I, II, III, IV, V, VIA, VIb, VII, VIII, and IX as identified in table 1 of §176.170(c) of this chapter, and limited to conditions of use E, F, and G described in table 2 of §176.170 of this chapter. 4. As emulsifiers and/or surface-active agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with §177.1640(c) of this chapter.</td>
</tr>
<tr>
<td>Alkyl mono- and disulfonic acids, sodium salts (produced from n-alkanes in the range of C&lt;sub&gt;10&lt;/sub&gt; to C&lt;sub&gt;18&lt;/sub&gt; with not less than 50 percent C&lt;sub&gt;14&lt;/sub&gt;±C&lt;sub&gt;16&lt;/sub&gt;).</td>
<td>For use only at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with §177.1640(c) of this chapter.</td>
</tr>
</tbody>
</table>

§ 178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as emulsifiers and/or surface-active agents 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 quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface-active agent 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 conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dicyclohexylamine and its salts of fatty acids derived from animal or vegetable oil. Dicyclohexylamine nitrite. Morpholine and its salts of fatty acids derived from animal or vegetable oils.</td>
<td>Propylene glycol.</td>
</tr>
<tr>
<td>(2) Adjuvants employed in the application and use of corrosion inhibitors:</td>
<td></td>
</tr>
<tr>
<td>List of substances</td>
<td>Limitations</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Propylene glycol.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(c) List of substances:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>α-Alkyl-, α-alkeny-, and α-alkylaryl-omega-hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of α-(2,4,6-trisobutylphenyl)-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of α-(Z)-9-octadecenyl-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and α-alkyl(C&lt;sub&gt;16&lt;/sub&gt;±C&lt;sub&gt;18&lt;/sub&gt;)-omega-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles.</td>
<td>For use only at levels not to exceed 0.5 pct by weight of coatings complying with §175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in §178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.</td>
</tr>
<tr>
<td>n-Alkylbenzenesulfonic acid (alkyl group consisting of not less than 95 percent C&lt;sub&gt;10&lt;/sub&gt; to C&lt;sub&gt;16&lt;/sub&gt;) and its ammonium, calcium, magnesium, potassium, and sodium salts.</td>
<td>For use only: 1. As provided in §176.170 of this chapter. 2. At levels not to exceed 2 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1860 of this chapter. 3. As emulsifiers in vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contains food safe of the Types I, II, III, IV, V, VIA, VIb, VII, VIII, and IX as identified in table 1 of §176.170(c) of this chapter, and limited to conditions of use E, F, and G described in table 2 of §176.170 of this chapter. 4. As emulsifiers and/or surface-active agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with §177.1640(c) of this chapter.</td>
</tr>
<tr>
<td>Alkyl mono- and disulfonic acids, sodium salts (produced from n-alkanes in the range of C&lt;sub&gt;10&lt;/sub&gt; to C&lt;sub&gt;18&lt;/sub&gt; with not less than 50 percent C&lt;sub&gt;14&lt;/sub&gt;±C&lt;sub&gt;16&lt;/sub&gt;).</td>
<td>For use only at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with §177.1640(c) of this chapter.</td>
</tr>
<tr>
<td>List of substances</td>
<td>Limitations</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>alpha Olefin sulfonate (alkyl group is in the range of C\textsubscript{10}–C\textsubscript{18} with not less than 50 percent C\textsubscript{14}–C\textsubscript{16} with not less than 50 percent C\textsubscript{14}–C\textsubscript{16}, ammonium, calcium, magnesium, potassium, and sodium salts.)</strong></td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. In acrylonitrile-butadiene copolymers identified in §177.2600(c)(4)(i) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not to exceed 1 percent by weight of acrylic coatings complying with §175.300(b)(3)(xx) of this chapter and having a maximum thickness of 0.051 millimeter (0.002 inch). The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>3. At levels not to exceed 2 percent by weight of vinyl chloride copolymer coatings having a maximum thickness of 0.051 millimeter (0.002 inch) and complying with §175.300(b)(3)(xxv) of this chapter. The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>4. As provided in §175.105 of this chapter.</td>
</tr>
<tr>
<td><strong>alpha-sulfo-omega-(dodecyloxy)poly(oxyethylene) ammonium salt (CAS Reg. No. 30174–67–5).</strong></td>
<td>For use only as an emulsifier at levels not to exceed 0.3 percent by weight of styrene-butadiene copolymer coatings for paper and paperboard complying with §176.170 of this chapter.</td>
</tr>
<tr>
<td><strong>Ammonium salt of epoxidized oleic acid, produced from epoxidized oleic acid (predominantly dihydroxyoctaerics and acetoxhydroxyoctaerics acids) meeting the following specifications: Acid number 160–180, saponification number 210–235, iodine number 2–15, and epoxy groups 0–0.4 percent.</strong></td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. As a polymerization emulsifier at levels not to exceed 1.5 percent by weight of vinyl chloride polymers used as components of nonfood articles complying with §§175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter. Such vinyl chloride polymers are limited to polyvinyl chloride and/or vinyl chloride copolymers complying with §177.1980 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. As a polymerization emulsifier at levels not to exceed 1.5 percent by weight of vinyl chloride-vinyl acetate copolymers used as components of nonfood articles complying with §§175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter.</td>
</tr>
<tr>
<td><strong>alpha-(p-Dodecylphenyl)-omega-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 103–111 and that are produced by the esterification of the condensation product of 1 mole of n-dodecyl alcohol with 4–4.5 moles of ethylene oxide.</strong></td>
<td>For use only as an emulsifier at levels not to exceed 5 percent by weight of polymers intended for use in coatings.</td>
</tr>
<tr>
<td></td>
<td>1. At levels not to exceed 10 micrograms/in\textsuperscript{2} (0.16 mg/dm\textsuperscript{2}) in vinylidene chloride copolymer or homopolymer coatings applied to films of propylene polymers complying with §177.1520 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not to exceed 14 micrograms/in\textsuperscript{2} (0.21 mg/dm\textsuperscript{2}) in vinylidene chloride copolymer or homopolymer coatings applied to films of polyethylene phthalate polymers complying with §177.1630 of this chapter.</td>
</tr>
<tr>
<td><strong>Naphthalene sulfonic acid-formaldehyde condensate, sodium salt (CAS Reg. No. 9084–06–4).</strong></td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. In acrylonitrile-butadiene copolymers identified in §177.2600(c)(4)(i) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not to exceed 1 percent by weight of acrylic coatings complying with §175.300(b)(3)(xx) of this chapter and having a maximum thickness of 0.051 millimeter (0.002 inch). The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>3. At levels not to exceed 2 percent by weight of vinyl chloride copolymer coatings having a maximum thickness of 0.051 millimeter (0.002 inch) and complying with §175.300(b)(3)(xxv) of this chapter. The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of §176.170(c) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>4. As provided in §175.105 of this chapter.</td>
</tr>
</tbody>
</table>
### § 178.3400

#### List of substances

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>α-(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 62–72 and that are produced by the esterification of α-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) complying with the identity prescribed in §178.3400(c) and having an average poly(oxyethylene) content of 9–10 moles.</td>
<td>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acyrlic polymers intended for use as coatings for paper and paperboard. For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.</td>
</tr>
<tr>
<td>α-(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 98–110 and that are produced by the esterification of α-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) complying with the identity prescribed in §178.3400(c) and having an average poly(oxyethylene) content of 45–55 moles.</td>
<td>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acyrlic polymers intended for use as coatings for paper and paperboard. For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.</td>
</tr>
<tr>
<td>α-(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.</td>
<td>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acyrlic polymers intended for use as coatings for paper and paperboard. For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.</td>
</tr>
<tr>
<td>a-(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) sulfate, ammonium or sodium salt: the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content average 4 moles.</td>
<td>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acyrlic polymers intended for use as coatings for paper and paperboard. For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.</td>
</tr>
<tr>
<td>Poly[(methylene- p- nonylphenoxy) poly(oxypropylene)(4±12 moles) propanol] of minimum molecular weight 3500. Poly(oxypropylene) (45–48 moles) block polymer with poly(oxyethylene). The finished block polymers meet the following specifications: Average molecular weight 11,000–18,000; hydroxyl number 6.2–10.2; cloud point above 100 °C for 10 pct solution.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate) meeting the following specifications: Saponification number 40–50, acid number 0–2, hydroxyl number 60–108, oxyethylene content 70–74 pct.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate) meeting the following specifications: Saponification number 41±52, oxyethylene content 66–70.5 pct.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 60 conforming to the identity prescribed in §172.836 of this chapter.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 65 conforming to the identity prescribed in §172.838 of this chapter.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 80 conforming to the identity prescribed in §172.840 of this chapter.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Polysorbate 85 (polyoxyethylene (20) sorbitan trioleate) meeting the following specifications: Saponification number 80–95, oxyethylene content 46–50 percent.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium 1,4-dicyclohexyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium 1,4-dihexyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium 1,4 diisobutyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium dioctyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium 1,4-dipentyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium 1,4-ditridecyl sulfosuccinate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium lauryl sulfate.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxypolyethoxylatesulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C8–C16.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
<tr>
<td>Sorbitan monolaurate meeting the following specifications. Saponification number 153–170; and hydroxyl number 330–360. Sorbitan monoleate meeting the following specifications: Saponification number 145–160; and hydroxyl number 193–210. Sorbitan monopalmitate meeting the following specifications: Saponification number 140–150; and hydroxyl No. 275–305. Sorbitan monostearate conforming to the identity prescribed in §172.842 of this chapter. Sorbitan trioleate meeting the following specifications: Saponification No. 170–190; and hydroxyl No. 55–70.</td>
<td>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings.</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS § 178.3480

List of substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitan tristearate meeting the following specifications: Saponeification No. 176–188; and hydroxyl No. 66–80. Sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354–45–5).</td>
<td>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acrylic polymers intended for use as coatings for paper and paperboard. For use only at levels not to exceed 5 percent by weight of the total coating monomers used in the emulsion polymerization of polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard.</td>
</tr>
<tr>
<td>Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by the condensation of 1 mole of nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).</td>
<td>For use only as a polymerization emulsifier for resins applied to tea-bag material.</td>
</tr>
<tr>
<td>Tetrasodium N-(1,2-dicarboxyethyl)-N-octadecyl-sulfosuccinate</td>
<td></td>
</tr>
<tr>
<td>α-Tridecyl-omega-hydroxy(poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 58–70 and that are produced by the esterification of the condensation product of one mole of “oxo” process tridecyl alcohol with 9–10 moles of ethylene oxide.</td>
<td></td>
</tr>
</tbody>
</table>

(d) The provisions of this section are not applicable to emulsifiers and/or surface-active agents listed in §175.105(c)(5) of this chapter and used in food-packaging adhesives complying with §175.105 of this chapter.

§178.3450 Esters of stearic and palmitic acids.

The ester stearyl palmitate or palmityl stearate or mixtures thereof may be safely used as adjuvants in food-packaging materials when used in accordance with the following prescribed conditions:

(a) They are used or intended for use as plasticizers or lubricants in polyethylene intended for use in contact with food.
(b) They are added to the formulated polymer prior to extrusion.
(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

§178.3480 Fatty alcohols, synthetic.

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in §172.864 of this chapter, except as provided in paragraph (c) of this section.
(b) It is used or intended for use as follows:
(1) As substitutes for the corresponding naturally derived fatty alcohols permitted for use as components of articles intended for use in contact with food by existing regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter: Provided, That the use is in compliance with any prescribed limitations.
(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted for use as components of food-contact articles.

(c) Synthetic fatty alcohols identified in paragraph (c)(1) of this section may contain not more than 0.8 weight percent of total diols as determined by a method titled “Diols in Monohydroxy Alcohol by Miniature Thin Layer Chromatography (MTLC),” which is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) Synthetic fatty alcohols. (i) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl alcohols meeting the specifications and definition prescribed in §172.864 of this chapter, except that they may contain not more than 0.8 weight percent total diols.

(ii) Lauryl, myristyl, cetyl, and stearyl alcohols manufactured by the process described in §172.864(a)(2) of this chapter such that lauryl and myristyl alcohols meet the specifications in §172.864(a)(1)(i) of this chapter, and cetyl and stearyl alcohols meet the specifications in §172.864(a)(1)(ii) of this chapter.

(2) Conditions of use. (i) Synthetic fatty alcohols as substitutes for the corresponding naturally derived fatty alcohols permitted for use in compliance with §178.3910.

(ii) Synthetic lauryl alcohol as a substitute for the naturally derived lauryl alcohol permitted as an intermediate in the synthesis of sodium lauryl sulfate used in compliance with §178.3400.

§ 178.3500 Glycerin, synthetic.

Synthetic glycerin may be safely used as a component of articles intended for use in packaging materials for food, subject to the provisions of this section:

(a) It is produced by the hydrogenolysis of carbohydrates, and shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used in a quantity not to exceed that amount reasonably required to produce its intended physical or technical effect, and in accordance with any limitations prescribed by applicable regulations in parts 174, 175, 176, 177, 178 and 179 of this chapter. It shall not be intended to, nor in fact accomplish, any direct physical or technical effect in the food itself.

§ 178.3505 Glyceryl tri-(12-acetoxy-stearate).

Glyceryl tri-(12-acetoxy-stearate) (CAS Reg. No. 139-43-5) may be safely used as a component 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 additive is applied to the surface of calcium carbonate at a level not to exceed 1 weight-per cent of the total mixture.

(b) The calcium carbonate/glyceryl tri-(12-acetoxy-stearate) mixture is used as an adjuvant in polymers in contact with nonfatty foods at a level not to exceed 20 weight-percent of the polymer.

[50 FR 1503, Jan. 11, 1985]

§ 178.3520 Industrial starch-modified.

Industrial starch-modified may be safely used as a component 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) Industrial starch-modified is identified as follows:

(i) A food starch-modified or starch or any combination thereof that has been modified by treatment with one of the reactants hereinafter specified, in an amount reasonably required to achieve the desired functional effect but in no event in excess of any limitations prescribed, with or without subsequent treatment as authorized in §172.892 of this chapter.
### List of reactants

<table>
<thead>
<tr>
<th>Reactant</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium persulfate, not to exceed 0.3 pct. or in alkaline starch not to exceed 0.6 pct.</td>
<td>Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.</td>
</tr>
<tr>
<td>(4-Chlorobutene-2) trimethylammonium chloride, not to exceed 5 pct.</td>
<td>Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.</td>
</tr>
<tr>
<td>β-Diethylaminoethyl chloride hydrochloride, not to exceed 4 pct. Dimethylaminoethyl methacrylate, not to exceed 3 pct. Dimethyl ethylene urea, not to exceed 0.375 pct</td>
<td>Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.</td>
</tr>
<tr>
<td>2,3-Epoxypropyltrimethylammonium chloride, not to exceed 5 pct. Ethylene oxide, not to exceed 3 pct of reacted ethylene oxide in finished product. Phosphoric acid, not to exceed 6 pct and urea, not to exceed 20 pct.</td>
<td>Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging and as surface sizing and coating for paper and paperboard that contact food only of Types IV-A, V, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter.</td>
</tr>
</tbody>
</table>

### List of reactants

<table>
<thead>
<tr>
<th>Reactant</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrylamide and [2-(methacryloyloxy) ethyl]trimethylammonium methyl sulfate, such that the finished industrial starch-modified shall contain:</td>
<td>For use only as a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact food, and used at a level not to exceed 0.25 pct by weight of the finished dry paper and paperboard fibers.</td>
</tr>
<tr>
<td>1. Not more than 60 weight percent vinyl copolymer (of which not more than 32 weight percent is [2-(methacryloyloxy)ethyl]trimethylammonium methyl sulfate).</td>
<td>(ii) An electron beam source at a maximum energy of 7 million electron volts of ionizing radiation, maximum absorbed dose not to exceed 5.0 megarads.</td>
</tr>
<tr>
<td>2. Not more than 0.20 pct residual acrylamide.</td>
<td></td>
</tr>
<tr>
<td>3. A minimum nitrogen content of 9.0 pct.</td>
<td></td>
</tr>
</tbody>
</table>

### List of reactants

<table>
<thead>
<tr>
<th>Reactant</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol (400) dilaurate.</td>
<td>(b) The following adjuvants may be used as surface-active agents in the processing of industrial starch-modified: Polyethylene glycol (400) monolaurate. Polyoxymethylene (4) lauryl ether.</td>
</tr>
<tr>
<td>Polyethylene glycol (400) monolaurate.</td>
<td>(b) The following adjuvants may be used as surface-active agents in the processing of industrial starch-modified: Polyethylene glycol (400) dilaurate. Polyethylene glycol (400) monolaurate. Polyoxymethylene (4) lauryl ether.</td>
</tr>
<tr>
<td>Polyoxymethylene (4) lauryl ether.</td>
<td></td>
</tr>
</tbody>
</table>

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

1. Substances generally recognized as safe for use in food.
2. Substances used in accordance with the provisions of a prior sanction or approval.
3. Substances identified in this paragraph (a)(3).

(b) Synthetic isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.


§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

1. Substances generally recognized as safe for use in food.
2. Substances used in accordance with the provisions of a prior sanction or approval.
3. Substances identified in this paragraph (a)(3).

(b) Synthetic isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Synthetic isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.


Substances Limitations

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum stearoyl benzoyl hydroxide</td>
<td>For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil. For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.</td>
</tr>
<tr>
<td>N,N-Bis(2-ethylhexyl)-ar-methyl-1H-benzotriazole-1-methanamine (CAS Reg. No. 94270-86-7).</td>
<td>Do.</td>
</tr>
<tr>
<td>BHA.</td>
<td>Do.</td>
</tr>
<tr>
<td>BHT.</td>
<td>Do.</td>
</tr>
<tr>
<td>o-Butyl-omega-hydroxypropyloxyethylene poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.</td>
<td>Do.</td>
</tr>
<tr>
<td>o-Butyl-omega-hydroxypropyloxyethylene; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.</td>
<td>Do.</td>
</tr>
<tr>
<td>Castor oil</td>
<td>Do.</td>
</tr>
<tr>
<td>Castor oil, dehydrated</td>
<td>Do.</td>
</tr>
<tr>
<td>Castor oil, partially dehydrated</td>
<td>Do.</td>
</tr>
</tbody>
</table>

Addition to food not to exceed 10 parts per million.
Food and Drug Administration, HHS

\section*{Substances and Limitations}

\begin{tabular}{|l|l|}
\hline
\textbf{Substances} & \textbf{Limitations} \\
\hline
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), which may contain up to 7 percent by weight 1,6-hexanediol (CAS Reg. No. 629-11-8), where the alkyl groups are derived from hydrogenated tallow fatty acids \((C_{16}-C_{18})\) and where the aluminum silicate is derived from bentonite. & For use only as a gelling agent in mineral oil lubricants at a level not to exceed 15 percent by weight of the mineral oil. \\
Dimethyl polysiloxane (viscosity greater than 300 centistokes) ... & Addition to food not to exceed 1 part per million. \\
Di \((\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\nu\n\hline
\end{tabular}
§ 178.3600 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester identified in §172.816(a) of this chapter may be safely used as a processing aid (filter aid) in the manufacture of starch, including industrial starch-modified complying with §178.3520, intended for use as a component of articles that contact food.

§ 178.3610 α-Methylstyrene-vinyltoluene resins, hydrogenated.

Hydrogenated α-methylstyrene-vinyltoluene copolymer resins having a molar ratio of 1 α-methylstyrene to 3 vinyltoluene may be safely used as components of polyolefin film intended for use in contact with food, subject to the following provisions:

(a) Hydrogenated α-methylstyrene-vinyltoluene copolymer resins have a drop-softening point of 125° to 165 °C and a maximum absorptivity of 0.17 liter per gram centimeter at 266 nanometers, as determined by methods titled “Determination of Softening Point (Drop Method)” and “Determination of Unsaturation of Resin 1977,” 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) The polyolefin film is produced from olefin polymers complying with §177.1520 of this chapter, and the average thickness of the film in the form in which it contacts food does not exceed 0.002 inch.

§ 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in § 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in parts 170 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b)(1) of this section may be used as provided in paragraph (b)(2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," 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, disregarding the last two sentences of that procedure and substituting therefore the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260–350 μm, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280–350 μm, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(ii) Ultraviolet absorbance limits as follows:

<table>
<thead>
<tr>
<th>Wavelength (μm)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280 to 289</td>
<td>4.0</td>
</tr>
<tr>
<td>290 to 299</td>
<td>3.3</td>
</tr>
<tr>
<td>300 to 329</td>
<td>2.3</td>
</tr>
<tr>
<td>330 to 350</td>
<td>0.8</td>
</tr>
</tbody>
</table>

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specification" on page 66 of the "Journal of the Association of Official Agricultural Chemists," Volume 45 (February 1962) (which is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408).

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and §§ 178.3570 and 178.3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c)(1) of this section may be used as provided in paragraph (c)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450 °F minimum.

(ii) Color 5.5 maximum as determined by ASTM method D1500-82, "Standard Test Method for ASTM Color of Petroleum Products (ASTM Color Scale)," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.
(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c)(3) of this section:

<table>
<thead>
<tr>
<th>Wavelength (µm)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>260 to 289</td>
<td>0.7</td>
</tr>
<tr>
<td>290 to 299</td>
<td>0.6</td>
</tr>
<tr>
<td>300 to 359</td>
<td>0.4</td>
</tr>
<tr>
<td>360 to 400</td>
<td>0.9</td>
</tr>
</tbody>
</table>

(2) The mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§175.105 and 176.210 of this chapter and §178.3910 (for use only in rolling of metallic foil and sheet stock), §§176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic material such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified iso-octane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, and preferably 1,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately ¾-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeter ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy 1 ±0.05 at 0.4 absorbance.

Wavelength accuracy, ±1 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and

1As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HF5-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suit 700, Washington, DC 20004.
methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified iso-octane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and n-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in iso-octane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to iso-octane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 290 and 400 microns. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by percolation through activated silica gel or by distillation.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. 10 percent benzene in iso-octane. Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with iso-octane, with mixing.

2. 20 percent benzene in iso-octane. Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with iso-octane, with mixing.

3. Acetone-benzene-water mixture. Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Absorbance (maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>261.5</td>
<td>1.00</td>
</tr>
<tr>
<td>270</td>
<td>.20</td>
</tr>
<tr>
<td>275</td>
<td>.09</td>
</tr>
<tr>
<td>280</td>
<td>.06</td>
</tr>
<tr>
<td>300</td>
<td>.015</td>
</tr>
</tbody>
</table>

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 200 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160°C ±1°C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60–180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60–180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160°C ±1°C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate
prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-milliliter glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.0 absorbance per centimeter path length between 280 µm and 400 µm when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.02 in the wavelength range from 280 µm to 400 µm; the absorbance per centimeter path length following the complete procedure should not exceed 0.02 in the wavelength range from 280 µm to 400 µm. If in either spectrum the characteristic benzene peaks in the 250 µm–260 µm region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 30 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stopped.) Add 350 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of preequilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 400 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off and discard the aqueous layer.

Shake the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layer. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of n-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 µm–400 µm (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter path length exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the remaining isooctane.
methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of approximately 5 milliliters. Add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residue.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and preset the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 2-3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane. Swirl the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2-3 milliliters per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds from the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under “Reagents and Materials” for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of n-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under “Organic solvents.” Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 μm–400 μm. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 μm–260 μm region, evaporate the solution to remove benzene by the procedure under “Organic solvents.” Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 371 °C, with a maximum residue not to exceed 2 percent, as determined by ASTM method D86-82, “Standard Method for Distillation of Petroleum Products,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.
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(i) Ultraviolet absorbance limits as follows determined by the method described in paragraph (d)(3) of this section.

<table>
<thead>
<tr>
<th>Wavelength (µm)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280 to 299</td>
<td>2.3</td>
</tr>
<tr>
<td>300 to 319</td>
<td>1.2</td>
</tr>
<tr>
<td>320 to 359</td>
<td>0.8</td>
</tr>
<tr>
<td>360 to 400</td>
<td>0.3</td>
</tr>
</tbody>
</table>

(ii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34(f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. Apparatus. A. Assorted beakers, separatory funnels fitted with tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter × 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item 1E below.

D. A chromatographic column made from nominal 1.7 centimeters outside diameter × 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a 25 centimeters outside diameter × 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item 1E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I. C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(NOTE: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280–400 µm with a spectral slit width of 2 µm or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within ±0.01 and accurate within ±0.05. Wavelength measurements shall be repeatable with ±0.2 µm and accurate within ±10 µm. Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 µm, using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.00±0.005 centimeter or better.

II. Purity of reagents and materials. Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall be tested for purity in accordance with the instruction given under "Reagents and Materials" in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. Reagents and materials—A. Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and n-hexadecane designated shall pass the following test: To the specified quantity of solvent in a 150-milliliter beaker, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of n-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 µm.

1. Isooctane (2,2,4-trimethylpentane). Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.
2. Benzene. Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. Cyclohexane. Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. Nitromethane. Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. n-Hexadecane. Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. Other materials—

1. Pyrene standard reference. Pyrene, reagent grade, melting point range 150-152 °C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 5.0 milligrams per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. This absorbance will be approximately 0.28.

2. Chrysene solution. Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. Nitrogen gas. Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. Silica gel. 100-200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in an oven at 130 °C for 16 hours. Upon removal from heat, store at atmospheric pressure over 80 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000 °F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams ± 1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters × 75 centimeters) described under "Apparatus" in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed, add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33 percent benzene and 66 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

b. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

g. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (NOTE: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100-160 mesh. Activation and testing of this
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1. Weigh out 20.0 grams ±0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock fitted with a tetrafluoroethylene polymer stopcock on the column. Transfer the n-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10–15 milliliters).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker. Evaporate until only 1 milliliter of the solvent residues by carrying out the procedure without a sample.

3. The procedure may be repeated four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker covering each extract in the 150-milliliter beaker. Evaporate until only 1 milliliter of the solvent residues by carrying out the procedure without a sample.

4. Weigh 50 grams ±1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters × 7.5 centimeters) described under “Apparatus” in C under I above. (NOTE: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under “Apparatus” in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the n-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10–15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33% percent benzene and 66% percent isooctane by volume) to the reservoir, and continue the percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(Note: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of n-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under nitrogen pressure. The 500-milliliter reservoir described under “Apparatus” in E under I above is to be used to hold the elution solvents.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100- 200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitro-methane and 71 weight-percent silica gel.

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15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter x 115 centimeters column, described under "Apparatus" in D of i above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate.

Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed. Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of n-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(Note: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 m\textmu. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (m\textmu), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 m\textmu, then the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m\textmu) by the base-line technique described in ASTM method E169-63 (Re-approved 1981), "Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

\[
\text{Absorbance due to pyrene} = \frac{C_p \times S_a}{S_p}
\]

where:
- \(C_p\) = Calculated concentration of pyrene in sample solution;
- \(S_p\) = Concentration of pyrene reference standard solution in same units of concentration;
- \(S_a\) = Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

\[
\text{Pyrene content (p.p.m.)} = \frac{(200/1000) \times C}{20/1000} = 10C
\]

where:
- \(C\) = Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 m\textmu, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300 °F minimum.

(3) Final boiling point is 650 °F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

<table>
<thead>
<tr>
<th>Wavelength (Mµ)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280 to 289</td>
<td>4.0</td>
</tr>
<tr>
<td>290 to 299</td>
<td>3.3</td>
</tr>
<tr>
<td>300 to 329</td>
<td>2.3</td>
</tr>
<tr>
<td>330 to 360</td>
<td>.8</td>
</tr>
</tbody>
</table>

(c) The additive is used as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a plasticizer and absorber oil in the manufacture of polyolefin articles authorized for food contact use.</td>
<td>In an amount not to exceed that required to produce intended effect, consistent with good manufacturing practice.</td>
</tr>
<tr>
<td>As a lubricant of fibers of textiles authorized for food contact use.</td>
<td>At a use level not to exceed 0.15 percent by weight of finished fibers.</td>
</tr>
<tr>
<td>As a component of adhesives</td>
<td>Complying with § 175.105 of this chapter.</td>
</tr>
<tr>
<td>As a defoamer in the manufacture of paper and paperboard</td>
<td>Complying with § 176.210 of this chapter.</td>
</tr>
<tr>
<td>As a defoamer in coatings</td>
<td>Complying with § 176.200 of this chapter.</td>
</tr>
</tbody>
</table>

§ 178.3690 Pentaerythritol adipate-stearate.

Pentaerythritol adipate-stearate identified in paragraph (a) of this section may be safely used as a lubricant in the fabrication of rigid and semi-rigid polyvinyl chloride and/or vinyl chloride-propylene copolymers complying with §177.1980 of this chapter used as articles or components of articles that contact food, excluding food with alcohol content greater than 8 percent under conditions of use of E, F, and G described in table 2 in §175.300(d) of this chapter, subject to the provisions of this section.

(a) Identity. For the purpose of this section, pentaerythritol adipate-stearate is an ester of pentaerythritol with adipic acid and stearic acid and its associated fatty acids (chiefly palmitic), with adipic acid comprising 14 percent and stearic acid and its associated acids (chiefly palmitic) comprising 71 percent of the organic moieties.

(b) Specifications. Pentaerythritol adipate-stearate has the following specifications:


(3) Saponification number of 270-280 as determined by ASTM method D1387-78, “Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes” (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or
§ 178.3710 Petroleum wax.

Petroleum wax may be safely used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed in this section.

(b) Petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in §172.886(b) of this chapter:

<table>
<thead>
<tr>
<th>Ultraviolet absorbance per centimeter pathlength:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Millimicrons</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>280 to 289</td>
</tr>
<tr>
<td>290 to 299</td>
</tr>
<tr>
<td>300 to 359</td>
</tr>
<tr>
<td>360 to 400</td>
</tr>
</tbody>
</table>

(c) Petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(d) Petroleum wax may contain a total of not more than 1 weight percent of residues of the following polymers when such residues result from use of the polymers as processing aids (filter aids) in the production of the petroleum wax: Homopolymers and/or copolymers derived from one or more of the mixed n-alkyl (C12, C14, C16, and C18)
§ 178.3720 Petroleum wax, synthetic.

Synthetic petroleum wax may be safely used in applications and under the same conditions where naturally derived petroleum wax is permitted in subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in §172.888 of this chapter.

§ 178.3725 Pigment dispersants.

Subject to the provisions of this regulation, the substances listed in this section may be safely used as pigment dispersants in food-contact materials.

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethylolpropionic acid (CAS Reg. No. 4767–63–7)</td>
<td>For use only at levels not to exceed 0.45 percent by weight of the pigment.</td>
</tr>
<tr>
<td>Phosphorylated tall oil fatty acids (CAS Reg. No. 68604–99–9), prepared</td>
<td>For use only at levels not to exceed 1.0 percent by weight of the pigment.</td>
</tr>
<tr>
<td>by the reaction of dimethyl hydrogen phosphite with tall oil fatty acids.</td>
<td>For use only at levels not to exceed 0.45 percent by weight of the pigment.</td>
</tr>
<tr>
<td>Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, compd. with 1:1:1</td>
<td>For use only at levels not to exceed 0.5 percent by weight of the pigment.</td>
</tr>
<tr>
<td>Siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-ox</td>
<td></td>
</tr>
</tbody>
</table>


§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§561.310 and 561.340 of this chapter, or that are intended for use in contact with dried feed in compliance with §§193.60 and 193.390 of this chapter.


§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in paragraph (b) of this section may be safely used as plasticizers in polymeric substances 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.

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

(b) List of substances:
Substances Limitations

Butyl benzyl phthalate For use only:
1. As provided in §§175.105 and 176.180 of this chapter.
2. In polymeric substances used in food-contact articles complying with §175.300, §175.320, or §176.170 of this chapter: Provided, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate.
3. In polymeric substances used in other permitted food-contact articles: Provided, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and Provided further, That the finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 mg. per sq. in., as determined by the methods prescribed in §175.300(e) of this chapter.

1,3-Butylene glycol adipic acid polyester (1,700–2,200 molecular weight) terminated with a 16 percent by weight mixture of myristic, palmitic, and stearic acids.

For use at levels not exceeding 33 percent by weight of polyvinyl chloride homopolymers used in contact with food (except foods that contain more than 8 percent of alcohol) at temperatures not to exceed room temperature. The average thickness of such homopolymers in the form in which they contact food shall not exceed 0.004 inch.

Di(C5–C9 alkyl) adipate, in which the C5–C9 alkyl groups are derived from linear alpha olefins by the oxo process.

For use only under the conditions listed below, and excluding use as a component of resinous and polymeric coatings described in §175.300 of this chapter.
1. At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
2. At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of §176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
3. At levels not exceeding 35 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch.
4. At levels not exceeding 35 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of §176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.

Di-n-alkyl adipate made from C6, C8, C10 (predominately C6 and C10) or C8C10 synthetic fatty alcohols complying with §172.864 of this chapter.

For use only:
1. At levels not exceeding 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
2. At levels not exceeding 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of §176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
3. At levels not exceeding 35 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch.
4. At levels not exceeding 35 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of §176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.

Dicyclohexyl phthalate For use only:
1. As provided in §§175.105, 176.170, 176.180, and 177.1200 of this chapter.
2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with §177.1580 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pt by weight of total phthalates, calculated as phthalic acid.
<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Di(2-ethylhexyl) adipate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 ppt by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
</tr>
<tr>
<td></td>
<td>3. At levels not exceeding 35 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.</td>
</tr>
<tr>
<td></td>
<td>4. At levels not exceeding 35 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 40 ppt by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.</td>
</tr>
<tr>
<td>Diisononyl adipate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. At levels not exceeding 24 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not exceeding 24 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 ppt by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.</td>
</tr>
<tr>
<td>Diisononyl phthalate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. For use only at levels not exceeding 43 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact with food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, IV-B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
</tr>
<tr>
<td>Di(2-ethylhexyl) azelate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. At levels not exceeding 24 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.</td>
</tr>
<tr>
<td></td>
<td>2. At levels not exceeding 24 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty, nonalcoholic food having a fat and oil content not exceeding a total of 30 percent by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.</td>
</tr>
<tr>
<td>Dini-hexylazelate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. In polymeric substances used in contact with nonfatty food.</td>
</tr>
<tr>
<td></td>
<td>2. In polymeric substances used in contact with fatty food and limited to use at levels not exceeding 15 ppt by weight of such polymeric substance except as provided under limitation 3.</td>
</tr>
<tr>
<td></td>
<td>3. At levels greater than 15 but not exceeding 24 ppt by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F or G described in table 2 of § 176.170(c) of this chapter, with fatty food having a fat and oil content not exceeding a total of 30 ppt by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.</td>
</tr>
<tr>
<td>Dihexyl phthalate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. As provided in § 175.105 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. In articles that contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, IV-B, VI-B, and VIII.</td>
</tr>
<tr>
<td>Diphenyl phthalate</td>
<td>For use only:</td>
</tr>
<tr>
<td></td>
<td>1. As provided in § 175.105 of this chapter.</td>
</tr>
<tr>
<td></td>
<td>2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 ppt by weight of total phthalates, calculated as phthalic acid.</td>
</tr>
<tr>
<td>Epoxidized butyl esters of linseed oil fatty acids</td>
<td>Iodine number, maximum 5; oxirane oxygen, minimum 7.8 ppt.</td>
</tr>
<tr>
<td>Epoxidized linseed oil</td>
<td>Iodine number, maximum 5; oxirane oxygen, minimum 9 ppt.</td>
</tr>
<tr>
<td>Mineral oil, white.</td>
<td></td>
</tr>
</tbody>
</table>
§ 178.3750 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in §172.820(b) of this chapter.

(c) The use of the plasticizers in any polymeric substance or article subject to any regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

ню 197, 178 and 179 of this chapter must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

§ 178.3770 Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids.

Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The polyhydric alcohol esters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food-contact articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with §177.1980 of this chapter. Such esters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthofen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

(1) Dropping point 76° to 105°C, as determined by ASTM method D566-76 (Reapproved 1982), “Standard Test Method for Dropping Point of Lubricating Grease,” 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) Acid value 10 to 20, as determined by ASTM method D1386-78 (“Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes” (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(3) Saponification value 100 to 160, as determined by ASTM method D1387-78 (“Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes” (Revised 1979), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits as follows, as determined by the analytical method described in this subparagraph:

<table>
<thead>
<tr>
<th>Millimicrons</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>280 to 289</td>
<td>0.07</td>
</tr>
<tr>
<td>290 to 299</td>
<td>0.06</td>
</tr>
<tr>
<td>300 to 359</td>
<td>0.04</td>
</tr>
<tr>
<td>360 to 400</td>
<td>0.01</td>
</tr>
</tbody>
</table>

ANALYTICAL METHOD

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels, 250-milliliter, 500-milli- liter, 1,000-milliliter, and preferably 2,000- milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir, 1,000-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball joint at the top.

Chromatographic tube, 1,200 millimeters in length, inside diameter to be 16.5 millimeters ±0.5 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of
the column with the female joint is 1,255 millimeters. The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately ½-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jackets. Conical, for 500-milliliter and 1,000-milliliter separatory funnels. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24°40 joints, fitted with a drying tube, length optional.

Evaporation flasks (optional). A 250-milliliter or 500-milliliter capacity and a 1-liter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide) 2-liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Oil bath. Capable of heating to 90°C.

Spectrophotometric cells. Used quartz cells, optical pathlength in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons-400 millimicrons with spectral slit width of 0.2 millimicron or less; under instrument operating conditions for these absorbance measurements. The spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy, 1 ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

**As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949).** The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

**REAGENTS AND MATERIALS**

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane and benzene designated in the list following this paragraph shall pass the following test:

To be specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of benzene.) Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and n-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the milliliter of hexadecane residue in isooctane and make up to 25 milliliters volume. Determine the absorbance in the 1-centimeter pathlength cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter pathlength between 280 µm and 400 µm.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference point between 280 µm-400 µm. The absorbance per centimeter pathlength
shall not exceed 0.00 in this range. If necess-
ary, purify by filtering through a column
containing 100 grams of aluminum oxide (use
same grade as described below) in the lower
half of a 2-liter glass-stoppered flask, or else
in the upper half keeping the column at 150 °C.,
for a period of 15 hours or overnight. The
first 100 milliliters of eluate are used. Purifica-
tion can also be accomplished by distilla-
tion.
Dimethyl sulfoxide. Pure grade, clear,
water-white, m.p. 18° minimum. Dilute 120
milliliters of dimethyl sulfoxide with 240
milliliters of distilled water in a 500-milli-
liter separatory funnel, and allow to cool
to room temperature. Add 40 milliliters of
isooctane to the solution and extract by
shaking the funnel vigorously for 2 minutes.
Repeat the test omitting the dimethyl
sulfoxide.
Repetition of the test omitting the dimethyl
sulfoxide through four thicknesses of fluted
paper (18.5 centimeters, Schleicher &
Schuell, No. 597, or equivalent). If the initial
filtrate contains color fines, pass the same
filter through the same filter until a clear filtrate
is obtained. Protect the sulfoxide from air
and moisture during this operation by cov-
ering the solvent in the funnel and collection
flask with a layer of isooctane. Transfer the
filtrate to a 2-liter separatory funnel and
draw off the dimethyl sulfoxide through the
2-
liter distillation flask of the vacuum dis-
tillation assembly and distill at approxi-
mate 3-millimeter Hg pressure or less. Dis-
card the first 200-milliliter fraction of the
distillate and replace the distillate collec-
tion flask with a clean one.
At completion of the distillation, the rea-
tant should be stored in glass-stoppered bot-
tles since it is very hygroscopic and will
react with some metal containers in the
presence of air.
Phosphoric acid. 85 percent A.C.S. reagent
grade.
Aluminum oxide (80-200 mesh Woelm neutral
activity grade 1 [Brockmann], Alupharm Chemi-
cals, New Orleans, La., or equivalent). Pipette
1 milliliter of distilled water into a dry 250-
milliliter Erlenmeyer flask, or option-
ally into the evaporating flask. Wash the
first separatory funnel with the second 40-
milliliter isooctane extractive, and pass the
solvent in the funnel and collection
flask with a layer of isooctane. Then
wet out the inside surfaces. When this has
been done add 180 grams of the aluminum
oxide and shake until no lumps or wet spots
remain. Allow to stand at room temperature
for a period of 2 hours. At the end of this
time the water should be evenly distributed
throughout the aluminum oxide powder, and
it should have the same free flowing prop-
eties as the original material (flow velocity
with water 0.2 milliliter per minute). At this
point the aluminum oxide has an activity of
1 as expressed in Brockmann degrees, and
the amount of added water is 0.5 percent by
volume. This product is used in toto and as
is, without further screening.
Sodium sulfate, anhydrous, A.C.S. reagent
grade, preferably in granular form. For each
bottle of sodium sulfate reagent used, estab-
lish as follows the necessary sodium sulfate
prewash to provide such filters required in
the method: Place approximately 35 grams of
anhydrous sodium sulfate in a 30-milliliter
coarse, fritted-glass funnel or in a 65-milli-
meter filter funnel with glass wool plug.
Wash with successive 15-milliliter portions of
the indicated solvent until a 15-milliliter
portion of the wash shows 0.00 absorbance
per centimeter pathlength between 280 m
and 400 m. When tested as prescribed under
Food and Drug Administration, HHS

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"Organic solvents." Usually three portions of wash solvent are sufficient.

PROCEDURE

Before proceeding with analysis of a sample, determine the absorbance in a 1-centimeter path cell between 250 µm and 400 µm for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectrum after the complete procedure as prescribed. The absorbance per centimeter pathlength following the complete procedure should not exceed 0.04 in the wavelength range from 280 µm to 290 µm, inclusive, nor 0.02 in the wavelength range from 300 µm to 400 µm. If in either spectrum the characteristic benzene peaks in the 250 µm-260 µm region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again. Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stopped.) Add 150 milliliters of isooctane and shake to preequilirate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

In a 1-liter separatory funnel place a representative 25-gram sample of wax, add 50 milliliters of isooctane, heat gently, stir until the wax is in solution; add 100 milliliters of preequilibrated sulfoxide-phosphoric acid mixture and shake, making sure it remains in solution. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isoctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layer, filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask or optionally into the evaporation flask. Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of n-hexadecane and evaporate the isooctane using an aspirator vacuum under nitrogen and in an oil bath temperature of approximately 90 °C. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 30-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Reserve the residue for column chromatography on the aluminum oxide. Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube in with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 180 grams of the aluminum oxide and pour the adsorbent mixture into the chromatographic tube in approximately 30-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 180 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 80 centimeters in depth. Turn off the vacuum and remove the suction flask. Dissolve the hexadecane residue in 10 milliliters of warm benzene and decant the solution onto the column and allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 10-
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milliliter portions of benzene swirling the flask repeatedly each time to assure adequate washing of the residue. Fix the 1,000-milliliter reservoir onto the top of the chromatographic column. Just before the final 10-milliliter wash reaches the top of the adsorbent, add 670 milliliter of benzene to the reservoir and continue the percolation at the 2-3 milliliter per minute rate until a total of 670 milliliter of benzene has been utilized. Collect the eluate in a clean 1-liter Erlenmeyer flask (or optionally into a 1-liter evaporation flask). Allow the column to drain until most of the solvent mixture is removed. Add 1 milliliter of n-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under “Organic Solvents.” Quantitatively transfer the residue with isoctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isoctane as reference between 250 mu-280 mu. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 mu-400 mu region, evaporate the solution to remove benzene by the procedure under “Organic Solvents.” Dissolve the residue, transfer quantitatively, and adjust to volume in isoctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in paragraph (a) of this section, the wax meets the ultraviolet absorbance specifications.

(b) The polyhydric alcohol esters identified in this paragraph may be used as release agents in resinous and polymeric coatings for polyolefin films complying with §175.320 of this chapter. Such esters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthofen process) montan wax acids with equimolar proportions of ethylene glycol and 1,3-butane-diol:

(1) Dropping point 77–82 °C, as determined by ASTM method D566–76 (Reapproved 1982), “Standard Test Method for Dropping Point of Lubricating Grease,” which is incorporated by reference; the availability of this incorporation by reference is given in paragraph (a)(1) of this section. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.


(4) Ultraviolet absorbance limits specified in paragraph (a)(4) of this section, as determined by the analytical method described therein.

(c) The polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids, identified in paragraph (a) or (b) of this section, may also be used as a component of an aqueous dispersion of vinylidene chloride copolymers, subject to the conditions described in paragraphs (c)(1) and (2) of this section.

(1) The aqueous dispersion of the additive contains not more than 18 percent polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids, not more than 2 percent poly(oxyethylene) (minimum 20 moles of ethylene oxide) oleyl ether (CAS Reg. No. 9005-96-2), and not more than 1 percent poly(oxyethylene) (minimum 3 moles ethylene oxide) cetyl alcohols (CAS Reg. No. 9004-95-9).

(2) The aqueous dispersion described in paragraph (c)(1) of this section is used as an additive to aqueous dispersions of vinylidene chloride copolymers, regulated in §§175.300, 175.320, 175.360, 176.170, 176.180, and 177.1630 of this chapter, at levels not to exceed 1.5 percent (solids basis) in the finished coating.
§ 178.3780 Polyhydric alcohol esters of long chain monobasic acids.

Polyhydric alcohol esters of long chain monobasic acids identified in this section may be safely used as lubricants in the fabrication of polyvinyl chloride and/or polyvinyl chloride copolymer articles complying with §177.1980 of this chapter that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII identified in table 1 of §176.170(c) of this chapter under conditions of use E, F, and G described in table 2 in §176.170(c) of this chapter, subject to the provisions of this section.

(a) Identity. For the purpose of this section, polyhydric alcohol esters of long chain monobasic acids consist of polyhydric alcohol esters having number average molecular weights in the range of 1,050 to 1,700. The esters are produced by the reaction of either ethylene glycol or glycerol with long chain monobasic acids containing from 9 to 49 carbon atoms obtained by the ozonization of long chain alpha-olefins, the unreacted carboxylic acids in the formation of the glycerol esters being neutralized with calcium hydroxide to produce a composition having up to 2 percent by weight calcium. The alpha-olefins, obtained from the polymerization of ethylene, have 20 to 50 carbon atoms and contain a minimum of 75 percent by weight straight chain alpha-olefins and not more than 25 percent vinylidene compounds.

(b) Specifications. The polyhydric alcohol esters have the following specifications:

(1) Melting point of 60-80 °C for the ethylene glycol ester and 90-105 °C for the glycerol ester as determined by the Fisher-Johns method as described in “Semimicro Qualitative Organic Analysis—The Systematic Identification of Organic Compounds,” by Cheronis and Entrikin, 2d Ed., Interscience Publishers, NY, which is 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 inspection at the Office of the Federal
§ 178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in semirigid and rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers and/or from vinyl chloride copolymers complying with §177.1950, §177.1970, and/or §177.1980 of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polymer modifiers are identified as follows:

(1) Acrylic polymers identified in this subparagraph provided that such polymers contain at least 50 weight-percent of polymer units derived from one or more of the monomers listed in paragraph (a)(1)(i) of this section.

(i) Homopolymers and copolymers of the following monomers:
   - n-Butyl acrylate.
   - n-Butyl methacrylate.
   - Ethyl acrylate.
   - Methyl methacrylate.

(ii) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1)(i) of this section with one or more of the following monomers:
   - Acrylonitrile.
   - Butadiene.
   - α-Methylstyrene.
   - Styrene.
   - Vinylidene chloride.

(iii) Polymers identified in paragraphs (a)(1)(i) and (ii) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:
   - Acrylic acid.
   - 1,3-Butylene glycol dimethacrylate.
   - Divinylbenzene.
   - Methacrylic acid.

(iv) Mixtures of polymers identified in paragraph (a)(1)(i), (ii), and (iii) of this section; provided that no chemical reactions, other than addition reactions, occur when they are mixed.

(2) Polymers identified in paragraph (a)(1) of this section combined during their polymerization with butadiene-styrene copolymers; provided that no chemical reactions, other than addition reactions, occur when they are combined. Such combined polymers may contain 50 weight-percent or more of total polymer units derived from the butadiene-styrene copolymers.

(b) The polymer content of the finished plastic food-contact article consists of:

(1) Not less than 80 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section and not more than 5 weight-percent of polymer units derived from polymers identified in paragraph (a)(1) of this section and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers; or
(2) Not less than 50 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section, not more than 50 weight-percent of polymer units derived from homopolymers and/or copolymers of ethyl acrylate and methyl methacrylate, and not more than 30 weight-percent of polymer units derived from copolymers of methyl methacrylate, α-methylstyrene and acrylonitrile and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers.

(c) No chemical reactions, other than addition reactions, occur among the vinyl chloride polymers and the modifying polymers present in the polymer mixture used in the manufacture of the finished plastic food-contact article.

(d) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the 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, yields extractives not to exceed the limits prescribed in §177.1010(b)(1), (2), (3), and (4) of this chapter when tested by the methods prescribed in §177.1010(c) of this chapter.

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

§ 178.3800 Preservatives for wood.

Preservatives may be safely used on wooden articles that are used or intended for use in packaging, transporting, or holding raw agricultural products subject to the provisions of this section:

(a) The preservatives are prepared from substances identified in paragraph (b) of this section and applied in amounts not to exceed those necessary to accomplish the technical effect of protecting the wood from decay, mildew, and water absorption.

(b) The substances permitted are as follows:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper-8-quinolinolate.</td>
<td>Used singly or in combination so as to constitute not less than 50% of the solids. Do.</td>
</tr>
<tr>
<td>Mineral spirits.</td>
<td></td>
</tr>
<tr>
<td>Paraffin wax</td>
<td></td>
</tr>
<tr>
<td>Petroleum hydrocarbon resin, produced by the homo- and copolymerization of dienes and olefins of the aliphatic, allylic, and monobenzenoid arylalkene type from distillates of cracked petroleum stocks.</td>
<td>Not to exceed 50 p.p.m. in the treated wood, calculated as pentachlorophenol. As provided in §178.3870.</td>
</tr>
<tr>
<td>Pentachlorophenol and its sodium salt</td>
<td></td>
</tr>
<tr>
<td>Rosins and resin derivatives</td>
<td></td>
</tr>
<tr>
<td>Zinc salt of sulfonated petroleum.</td>
<td></td>
</tr>
</tbody>
</table>

§ 178.3850 Reinforced wax.

Reinforced wax may be safely used as an article or component of articles intended for use in producing, manufacturing, packing, processing, transporting, or holding food subject to the provisions of this section.

(a) Reinforced wax consists of petroleum wax to which have been added certain optional substances required in its production, or added to impart desired physical or technical properties.

(b) The quantity of any optional adjuvant substance employed in the production of or added to reinforced wax does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation provided in this section.

(c) Any substance employed in the production of reinforced wax, including 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 specification in such regulation.

(d) The substances and optional adjuvant substances employed in the production of or added to reinforced wax include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction for use in reinforced wax and used
§ 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:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erucamide (erucylamide).</td>
<td>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.</td>
</tr>
<tr>
<td>Formaldehyde, polymer with 1-naphthalenoI (CAS Reg. No. 25359-91-5).</td>
<td>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.</td>
</tr>
<tr>
<td>N,N'-Dioleylethylenediamine</td>
<td>For use only subject to the limitations prescribed for hydrogenated polybutene under §178.3740(b).</td>
</tr>
<tr>
<td>Oleyl palmmitamide.</td>
<td>For use only in application to the backing of pressure sensitive adhesive tapes at levels not to exceed 0.2 milligram per square centimeter (1.29 milligrams per square inch) of backing.</td>
</tr>
<tr>
<td>Polybutene, hydrogenated; complying with the identity prescribed under §178.3740(b). Polyvinyl acetate/vinyl octadecylcarbamate (CAS Reg. No. 70892-21-6) produced by the reaction between stochiometrically equivalent amounts of octadecyl isocyanate and vinyl alcohol/vinyl acetate copolymer; minimum average molecular weight is 500,000.</td>
<td></td>
</tr>
<tr>
<td>Rice bran wax</td>
<td></td>
</tr>
<tr>
<td>Saturated fatty acid amides manufactured from fatty acids derived from animal, marine, or vegetable fats and oils. Stearyl erucamide.</td>
<td></td>
</tr>
</tbody>
</table>

§ 178.3870 Rosins and rosin derivatives.

The rosins and rosin derivatives identified in paragraph (a) of this section may be safely 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 multicolurnar 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 dehydroabietic acid content of 2 percent, a minimum drop-softening point of 79 °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 phenanthenes (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 4 to 8, a drop-softening point of 102-110 °C, and a color of M or paler.
(ii) Glycerol ester of partially hydrogenated 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.
(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 7 to 18, a drop-softening point of 102-110 °C, and a color of K or paler.
(i) 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.
(xiii) Pentaerythritol ester of maleic anhydride-modified wood rosin, further modified by reaction with 4,4′-isopropyl-enediphenol-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 μm (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° to 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 to 12, a softening point of 80° to 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° to 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)(iv) 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 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.


(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:


§ 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.

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>α-Butyl-ω-hydroxy(poly(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.</td>
<td></td>
</tr>
<tr>
<td>α-Butyl-ω-hydroxy(poly(oxypropylene) (CAS Reg. No. 9003-13-6) having a minimum molecular weight of 1000.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>alpha-Alkyl-omega-hydroxy(poly(oxyethylene) produced by the condensation of 1 mole of C₉–C₁₆ straight chain primary alcohols with an average of 3 moles of ethylene oxide (CAS Reg. No. 6002-97-1).</td>
<td></td>
</tr>
<tr>
<td>Benzothiazole (CAS Reg. No. 95-14-7)</td>
<td></td>
</tr>
</tbody>
</table>
List of substances

Bis(hydrogenated tallow alkyl)amine (CAS Reg. No. 61789–79–5).

Bis(hydrogenated tallow alkyl)aminoethanol (CAS Reg. No. 116438–56–3).

N,N-Bis(2-hydroxyethyl)butylamine (CAS Reg. No. 102–79–4)

Tert-Butyl alcohol.

Di(2-ethylhexyl)phthalate.

Diethyl phthalate.

Diethylene glycol monobutylether (CAS Reg. No. 112±34–5).

Dimers, trimers, and/or their partial methyl esters; such dimers and trimers are of unsaturated C18 fatty acids derived from animal and vegetable fats and oils and/or tall oil, and such partial methyl esters meet the following specifications: Saponification value 180–200, acid value 70–130, and maximum iodine value 120.

Di-n-octyl sebacate.

Ethylenediaminetetraacetic acid, sodium salts.

Isopropyl alcohol.

Isopropyl laurate (CAS Reg. No. 10233–13–3)

For use at a level not to exceed 10 percent by weight of the finished lubricant formulation.

Isopropyl oleate.


Methyl esters of coconut oil fatty acids.

Methyl esters of fatty acids (C16–C18) derived from animal and vegetable fats and oils.

Polybutene, hydrogenated: complying with the identity prescribed under § 178.3740(b).

Polyethylene glycol (400) monostearate.

Polyisobutylene (minimum molecular weight 300).

Polyoxyethylated (5 moles) tallow amine (CAS Reg. No. 61791–26–2).

Polyvinyl alcohol.

Sodium nitrite ............................................................................... For use only as a rust inhibitor in lubricant formulations provided the total residual sodium nitrite on the metallic article in the form in which it contacts food does not exceed 0.007 milligram per square inch of metallic food-contact surface.


Synthetic alcohol mixture of straight- and branched-chain alcohols that have even numbers of carbon atoms in the range C4–C18 and that are prepared from ethylene, aluminum, and hydrogen such that the finished synthetic alcohol mixture contains not less than 75 pct of straight-chain primary alcohols and contains not less than 85 pct total C10 and C12 alcohols.

Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 pct normal alcohols; not less than 96.5 pct C12±C15 alcohols; and not more than 2.5 pct alpha, omega C13±C16 diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight, 207±4; hydroxyl number, 266–276.

Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 percent normal alcohols; not less than 93 pct C12–C13 alcohols; not more than 5 pct C14–C15 alcohols; and not more than 2.5 pct alpha, omega, C13–C16 diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications:

Molecular weight 194±5; hydroxyl number, 283–296.

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List of substances Limitations

Bis(hydrogenated tallow alkyl)amine (CAS Reg. No. 61789–79–5) Not to be used in combination with sodium nitrite.

Bis(hydrogenated tallow alkyl)aminoethanol (CAS Reg. No. 116438–56–3).

N,N-Bis(2-hydroxyethyl)butylamine (CAS Reg. No. 102–79–4) For use at a level not to exceed 10 percent by weight of the finished lubricant formulation.

Tert-Butyl alcohol.

Di(2-ethylhexyl)phthalate.

Diethyl phthalate.

Diethylene glycol monobutylether (CAS Reg. No. 112±34–5) For use at a level not to exceed 10 percent by weight of the finished lubricant formulation.

Dimers, trimers, and/or their partial methyl esters; such dimers and trimers are of unsaturated C18 fatty acids derived from animal and vegetable fats and oils and/or tall oil, and such partial methyl esters meet the following specifications: Saponification value 180–200, acid value 70–130, and maximum iodine value 120.

Di-n-octyl sebacate.

Ethylenediaminetetraacetic acid, sodium salts.

Isopropyl alcohol.

Isopropyl laurate (CAS Reg. No. 10233–13–3) For use at a level not to exceed 10 percent by weight of the finished lubricant formulation.

Isopropyl oleate.


Methyl esters of coconut oil fatty acids.

Methyl esters of fatty acids (C16–C18) derived from animal and vegetable fats and oils.

Polybutene, hydrogenated: complying with the identity prescribed under §178.3740(b).

Polyethylene glycol (400) monostearate.

Polyisobutylene (minimum molecular weight 300).

Polyoxyethylated (5 moles) tallow amine (CAS Reg. No. 61791–26–2).

Polyvinyl alcohol.

Sodium nitrite ............................................................................... For use only as a rust inhibitor in lubricant formulations provided the total residual sodium nitrite on the metallic article in the form in which it contacts food does not exceed 0.007 milligram per square inch of metallic food-contact surface.


Synthetic alcohol mixture of straight- and branched-chain alcohols that have even numbers of carbon atoms in the range C4–C18 and that are prepared from ethylene, aluminum, and hydrogen such that the finished synthetic alcohol mixture contains not less than 75 pct of straight-chain primary alcohols and contains not less than 85 pct total C10 and C12 alcohols.

Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 pct normal alcohols; not less than 96.5 pct C12±C15 alcohols; and not more than 2.5 pct alpha, omega C13±C16 diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight, 207±4; hydroxyl number, 266–276.

Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 percent normal alcohols; not less than 93 pct C12–C13 alcohols; not more than 5 pct C14–C15 alcohols; and not more than 2.5 pct alpha, omega, C13–C16 diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications:

Molecular weight 194±5; hydroxyl number, 283–296.
(3) Mineral oil conforming to the identity prescribed in § 178.3620(c).  

(4) Light petroleum hydrocarbons identified in paragraph (a)(4)(i) of this section: Provided, That the total residual lubricant on the metallic article in the form in which it contacts food meets the ultraviolet absorbance limits prescribed in paragraph (a) (4)(ii) of this section as determined by the analytical method described in paragraph (a) (4)(iii) of this section.

(i) Light petroleum hydrocarbons are derived by distillation from virgin petroleum stocks or are synthesized from petroleum gases. They are chiefly paraffinic, isoparaffinic, napthenic, or aromatic in nature, and meet the following specifications:

(a) Initial boiling point is 24 °C minimum and final boiling point is 288 °C maximum, as determined by ASTM method D86-82, “Standard Method for Distillation of Petroleum Products,” 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.

(b) Nonvolatile residue is 0.005 gram per 100 milliliters, maximum, as determined by ASTM method D381-80, “Standard Test Method for Existent Gum in Fuels by Jet Evaporation,” when the final boiling point is 121 °C or above and by ASTM method D1353-78, “Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products,” when the final boiling point is below 121 °C. These ASTM methods are incorporated by reference. The availability of these incorporations by reference is given in paragraph (a)(4)(ii)(a) of this section.

(c) Saybolt color 20 minimum as determined by ASTM method D156-82, “Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method),” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii)(a) of this section.

(d) Aromatic component content shall not exceed 32 percent.

(e) Conforms with ultraviolet absorbance limits prescribed in § 178.3620(c) as determined by the analytical method described therein.

(ii) Ultraviolet absorbance limits on residual lubricants are as follows:

<table>
<thead>
<tr>
<th>Wavelength (m)</th>
<th>Maximum absorbance per 5 centimeters optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>0.7</td>
</tr>
<tr>
<td>290–299</td>
<td>0.6</td>
</tr>
<tr>
<td>300–359</td>
<td>0.4</td>
</tr>
<tr>
<td>360–400</td>
<td>0.09</td>
</tr>
</tbody>
</table>

(iii) The analytical method for determining ultraviolet absorbance limits on residual lubricants is as follows:

GENERAL INSTRUCTIONS
Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent, residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS
Separatory funnels, 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks. Evaporation flask (optional), 250-milliliter or 500-milliliter capacity all-glass flask.
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equipped with standard-taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Special range 250 millimicrons–400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy, ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Soxhlet apparatus. 60-millimeter diameter body tubes fitted with condenser and 500-milliliter round-bottom boiling flask. A supply of paper thimbles to fit is required.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane (2,2,4-trimethylpentane) shall pass the following test:

Place 180 milliliters of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains.

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and n-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.01 per centimeter path length between 280 and 400 µ. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 µ–400 µ. The absorbance per centimeter path length shall not exceed 0.01 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.


<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Absorbance (maximal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>261.5</td>
<td>1.00</td>
</tr>
<tr>
<td>270</td>
<td>0.20</td>
</tr>
<tr>
<td>275</td>
<td>0.09</td>
</tr>
<tr>
<td>280</td>
<td>0.06</td>
</tr>
<tr>
<td>300</td>
<td>0.015</td>
</tr>
</tbody>
</table>

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 65 percent A.C.S. reagent grade.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-milliliter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 µ and 400 µ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

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As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949), which is 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 inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408. The accuracy is to be determined by comparison with the standard values at 210, 345, and 400 millimicrons.
Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without a metal sample. The absorbance per centimeter path length should not exceed 0.02 in the wavelength range from 280 μm to 400 μm.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stopped.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

**PROCEDURE**

Sample. Select metal foil or sheet stock for the test which has not been previously contaminated by careless handling or exposure to atmospheric dust and fumes. A commercial coil in the form supplied for spindle mounting in a packaging line or wrapping machine is most suitable. Strip off the outside turn of metal and discard. Carefully avoid contamination or damage from handling the metal (wear gloves). Remove a 16-18-foot length from the coil and place it on a flat surface protected by a length of new kraft paper. Cut four 15-foot strips from the sample, each 3 inches wide (avoid tearing the edges of the strips). Using a piece of suitable glass rod, roll the strips of metal into loose coils and insert each into a Soxhlet thimble. Each turn of coil should be visibly separated from the adjacent turn.

Extraction. Fill each of the four Soxhlet tubes with purified isooctane (see under heading "Reagents and Materials," above) until siphon action occurs and then refill the tube body. Supply heat to the boiling flask and allow extraction to continue for at least 8 hours or until repeated weighings of the dried and cooled coil show no further weight loss.

Combine the isooctane extracts from the four Soxhlet units in a suitable beaker, rinsing each tube and flask into the beaker with fresh purified solvent. Evaporate the solvent under an atmosphere of inert gas (nitrogen) to residual volume of 50-60 milliliters and transfer this solution to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of pre-equilibrated isooctane to give a total volume of the residue and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 300-milliliter portion of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliter of isooctane. Draw off and discard the aqueous layer. Wash each of the 80 milliliter extractives three times with 100-milliliter portions distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate pre-washed with isooctane (see sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of n-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in 5-centimeter pathlength cells compared to isooctane as reference between 280 μm-400 μm (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a metal sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the residue meets the ultraviolet absorbance specifications.

(b) The following substances may be used in surface lubricants used to facilitate the drawing, stamping, or forming of metallic articles from rolled foil or sheet stock by further processing provided that the total residual...
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lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.2 milligram per square inch of food-contact surface:

(1) Antioxidants used in compliance with regulations in parts 170 through 189 of this chapter.
(2) Substances identified in this subparagraph.

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetyl tributyl citrate.</td>
<td>Conforming to the identity prescribed in §181.28 of this chapter.</td>
</tr>
<tr>
<td>Acetyl triethyl citrate.</td>
<td>Conforming to the identity prescribed in §181.27 of this chapter.</td>
</tr>
<tr>
<td>Butyl stearate.</td>
<td></td>
</tr>
<tr>
<td>Castor oil.</td>
<td></td>
</tr>
<tr>
<td>Dibutyl sebacate.</td>
<td></td>
</tr>
<tr>
<td>Di(2-ethylhexyl) azelate.</td>
<td></td>
</tr>
<tr>
<td>Di(2-ethylhexyl) sebacate.</td>
<td></td>
</tr>
<tr>
<td>Dimethyl polysiloxane</td>
<td></td>
</tr>
<tr>
<td>Dipropylene glycol.</td>
<td></td>
</tr>
<tr>
<td>Epoxidized soybean oil</td>
<td></td>
</tr>
<tr>
<td>Fatty acids derived from animal and vegetable fats and oils, and salts of such acids, single or mixed, as follows: Aluminum. Magnesium. Potassium. Sodium. Zinc.</td>
<td>Conforming to the identity prescribed in §178.3620 (a) or (b).</td>
</tr>
<tr>
<td>Fatty alcohols, straight-chain with even number carbon atoms (C₁₀ or greater). Isobutyl stearate. Lanolin. Linoleic acid amide. Mineral oil</td>
<td></td>
</tr>
<tr>
<td>Mono-, di-, and tristearyl citrate. Oleic acid amide. Palmitic acid amide. Petrolatum</td>
<td>Conforming to the identity prescribed in §178.3700. For use only at levels not to exceed 0.5 percent by weight of the finished surface lubricant formulation.</td>
</tr>
<tr>
<td>Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C₁₁₋₁₄-alkylamines (CAS Reg. No. 80939-62-4). Polyethylene glycol (molecular weight 300 or greater).</td>
<td>Mono- and diethylene glycol content not to exceed a total of 0.2 pct.</td>
</tr>
<tr>
<td>Stannous stearate. Stearic acid amide. Stearyl stearate. Tetra(iso-methylene)[3,5-di-tert-butyl-4-hydroxyhydrocinnamate] methane (CAS Registry No. 6683-19-8). Triethylene glycol</td>
<td>For use at a level not to exceed 0.5 percent by weight of the finished surface lubricant formulation. Diethylene glycol content not to exceed 0.1 pct. Complying with §178.3710.</td>
</tr>
</tbody>
</table>

(c) The substances identified in paragraph (a)(2) of this section may be used in surface lubricants used to facilitate the drawing, stamping, and forming of metallic articles from rolled foil and 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 food-contact surface.

(d) Subject to any prescribed limitations, the quantity of surface lubricant used in the manufacture of metallic articles shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any technical effect in the food itself.

(e) The use of the surface lubricants in the manufacture of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter must comply with any specifications prescribed by such regulation for the finished form of the article.

(f) Any substance that is listed in this section and the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter shall comply...
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§ 178.3930 Terpene resins.

The terpene resins identified in paragraph (a) of this section may be safely used as components of polypropylene film intended for use in contact with food, and the terpene resins identified in paragraph (b) of this section may be safely used as components of polyolefin film intended for use in contact with food;

(a) Terpene resins consisting of the hydrogenated polymers of terpene hydrocarbons obtainable from sulfate turpentine and meeting the following specifications: Drop-softening point of 118.0°C ± 13°C; iodine value less than 20.

(b) Terpene resins consisting of polymers of beta-pinene and meeting the following specifications: Acid value less than 1; saponification number less than 1; color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.

§ 178.3940 Tetraethylene glycol di-(2-ethylhexoate).

Tetraethylene glycol di-(2-ethylhexoate) containing not more than 22 parts per million ethylene and/or diethylene glycols may be used at a level not to exceed 0.7 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with §177.1500 of this chapter.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

Subpart A [Reserved]

Subpart B—Radiation and Radiation Sources

Sec.
179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.
179.25 General provisions for food irradiation.
179.26 Ionizing radiation for the treatment of food.
179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.
179.39 Ultraviolet radiation for the processing and treatment of food.
179.41 Pulsed light for the treatment of food.

Subpart C—Packaging Materials for Irradiated Foods

179.45 Packaging materials for use during the irradiation of prepackaged foods.


SOURCE: 42 FR 14635, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Radiation and Radiation Sources

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

Sources of radiation for the purposes of inspection of foods, for inspection of packaged food, and for controlling food processing may be safely used under the following conditions:

(a) The radiation source is one of the following: