

## § 174.6

(c) The existence in this subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

(1) Substances generally recognized as safe in or on food.

(2) Substances generally recognized as safe for their intended use in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and §179.45 of this chapter.

(5) Food contact substances used in accordance with an effective pre-market notification for a food contact substance (FCN) submitted under section 409(h) of the act.

[42 FR 14534, Mar. 15, 1977, as amended at 67 FR 35731, May 21, 2002]

### § 174.6 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate, or that may be expected to migrate, into food at negligible levels may be reviewed under §170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in §170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]

## PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

### Subpart A [Reserved]

## 21 CFR Ch. I (4–1–16 Edition)

### Subpart B—Substances for Use Only as Components of Adhesives

Sec.

175.105 Adhesives.

175.125 Pressure-sensitive adhesives.

### Subpart C—Substances for Use as Components of Coatings

175.210 Acrylate ester copolymer coating.

175.230 Hot-melt strippable food coatings.

175.250 Paraffin (synthetic).

175.260 Partial phosphoric acid esters of polyester resins.

175.270 Poly(vinyl fluoride) resins.

175.300 Resinous and polymeric coatings.

175.320 Resinous and polymeric coatings for polyolefin films.

175.350 Vinyl acetate/crotonic acid copolymer.

175.360 Vinylidene chloride copolymer coatings for nylon film.

175.365 Vinylidene chloride copolymer coatings for polycarbonate film.

175.380 Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.

175.390 Zinc-silicon dioxide matrix coatings.

AUTHORITY: 21 U.S.C. 321, 342, 348, 379e.

SOURCE: 42 FR 14534, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 175 appear at 61 FR 14482, Apr. 2, 1996, 66 FR 56035, Nov. 6, 2001, and 70 FR 72074, Dec. 1, 2005.

### Subpart A [Reserved]

### Subpart B—Substances for Use Only as Components of Adhesives

#### § 175.105 Adhesives.

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations.

(2) The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

(i) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(ii) *In fatty and aqueous foods.* (a) The quantity of adhesive that contacts

**§ 175.105**

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances permitted for use in adhesives by prior sanction or approval and employed under the specific conditions of use prescribed by such sanction or approval.

(3) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adhesives during the packaging fabrication process.

(4) Color additives approved for use in food.

(5) Substances permitted for use in adhesives by other regulations in this subchapter and substances named in this subparagraph: *Provided, however*, That any substance named in this paragraph and covered by a specific regulation in this subchapter, must meet any specifications in such regulation.

Ammonium borate.

Substances	Limitations
Ammonium citrate. Ammonium persulfate. Ammonium polyacrylate. Ammonium potassium hydrogen phosphate. Ammonium silico-fluoride .....	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Ammonium sulfamate. Ammonium thiocyanate. Ammonium thiosulfate. Amyl acetate. Anhydroenneaheptitol. Animal glue as described in § 178.3120 of this chapter. 2-Anthraquinone sulfonic acid, sodium salt ..... Antimony oxide. Asbestos. Asphalt, paraffinic and naphthenic. Azelaic acid. Azo- <i>bis</i> -isobutyronitrile. Balata rubber. Barium acetate. Barium peroxide. Barium sulfate. Bentonite. Benzene (benzol). 1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethylethyl)-6-[[3-(1,1-dimethylethyl)-2-hydroxy-5-methylphenyl]methyl]-4-methyl-phenyl]ester (CAS Reg. No. 57569–40–1). 1,2-Benzisothiazolin–3–one (CAS Registry No. 2634–33–5) ..... Benzothiazyl disulfide. <i>p</i> -Benzoxyphenol ..... Benzoyl peroxide. Benzyl alcohol. Benzyl benzoate. Benzyl bromoacetate ..... <i>p</i> -Benzoyloxyphenol ..... BHA (butylated hydroxyanisole). BHT (butylated hydroxytoluene). Bicyclo[2.2.1]hept-2-ene-6-methyl acrylate. 2-Biphenyl diphenyl phosphate. Bis(benzoate- <i>O</i> )(2-propanolato)aluminum (CAS Reg. No. 105442–85–1)	For use only as polymerization-control agent.
1,2-Bis(3,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamoyl)hydrazine (CAS Reg. No. 32687–78–8). 1,3-Bis(2-benzothiazolylmercaptomethyl) urea. 4,4'-Bis( $\alpha,\alpha$ -dimethylbenzyl)diphenylamine. 2,6-Bis(1,1-dimethylethyl)-4-(1-methylpropyl)phenol (CAS Reg. No. 17540–75–9). 2,6-Bis (1-methylheptadecyl)- <i>p</i> -cresol. 4-[[4, 6-Bis(octylthio)6-Bis(octylthio)6-Bis(octylthio)- <i>s</i> -triazin-2-yl]amino]-2,6-di- <i>tert</i> -butylphenol (CAS Reg. No. 991–84–4). Bis(tri- <i>n</i> -butyltin) oxide ..... Bis(trichloromethyl)sulfone C.A. Registry No. 3064–70–8 ..... Borax. Boric acid. 2-Bromo-2-nitro-1, 3-propanediol (CAS Reg. No. 52–51–7) ..... Butanedioic acid, sulfo-1,4-di-(C <sub>9</sub> -C <sub>11</sub> alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093–88–9]).. 1,3-Butanediol. 1,4-Butanediol. 1,4-Butanediol modified with adipic acid. Butoxy polyethylene polypropylene glycol (molecular weight 900–4,200). Butyl acetate. Butyl acetyl ricinoleate. Butyl alcohol. Butylated reaction product of <i>p</i> -cresol and dicyclopentadiene ..... Butylated, styrenated cresols identified in § 178.2010(b) of this chapter. Butyl benzoate. Butyl benzyl phthalate. Butyldecyl phthalate ..... 1,3-Butylene glycoldiglycolic acid copolymer. <i>tert</i> -Butyl hydroperoxide.	For use as a stabilizer.  For use as preservative only.  For use as preservative only.  For use as preservative only. Do.  For use only as a reactant in the preparation of polyester resins. For use at a level not to exceed 2 percent by weight of the adhesive.  For use as an antioxidant and/or stabilizer only.  For use as preservative only. Do.  For use only as an antibacterial preservative. For use as a surface active agent in adhesives.
	As identified in § 178.2010(b) of this chapter.

Substances	Limitations
4,4'-Butylidenebis(6- <i>tert</i> -butyl- <i>m</i> -cresol).	
Butyl lactate.	
Butyloctyl phthalate.	
<i>p</i> - <i>tert</i> -Butylphenyl salicylate.	
Butyl phthalate butyl glycolate.	
<i>p</i> - <i>tert</i> -Butylpyrocatechol .....	For use only as polymerization-control agent.
Butyl ricinoleate.	
Butyl rubber polymer.	
Butyl stearate.	
Butyl titanate, polymerized.	
Butyraldehyde.	
Calcium ethyl acetoacetate.	
Calcium nitrate.	
Calcium metasilicate.	
Camphor.	
Camphor fatty acid esters.	
Candelilla wax.	
<i>epsilon</i> -Caprolactam-(ethylene-ethyl acrylate) graft polymer.	
Carbon black, channel process.	
Carbon disulfide-1,1'-methylenedipiperidine reaction product.	
Carbon tetrachloride.	
Carboxymethylcellulose.	
Castor oil, polyoxyethylated (4–84 moles ethylene oxide).	
Cellulose acetate butyrate.	
Cellulose acetate propionate.	
Ceresin wax (ozocerite).	
Cetyl alcohol.	
Chloracetamide.	
Chloral hydrate.	
Chlorinated liquid <i>n</i> -paraffins with chain lengths of C <sub>10</sub> -C <sub>17</sub> , containing 40–70 percent chlorine by weight.	
Chlorinated pyridine mixture with active ingredients consisting of 2,3,5,6-tetrachloro-4-(methylsulfonyl) pyridine, 2,3,5,6-tetrachloro-4-(methylsulfinyl) pyridine and pentachloropyridine.	For use as preservative only.
Chlorinated rubber polymer (natural rubber polymer containing approximately 67 percent chlorine).	
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride .....	For use as preservative only.
Chlorobenzene.	
4-Chloro-3,5-dimethylphenol ( <i>p</i> -chloro- <i>m</i> -xlenol) .....	For use as preservative only.
4-Chloro-3-methylphenol .....	Do.
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172–55–4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682–20–4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935–90–2). The mixture may contain magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in polymer latex emulsions.
Chloroform.	
Chloroprene.	
Chromium caseinate.	
Chromium nitrate.	
Chromium potassium sulfate.	
Cobaltous acetate.	
Coconut fatty acid amine salt of tetrachlorophenol .....	For use as preservative only.
Copal.	
Copper 8-quinolinolate .....	For use as preservative only.
Coumarone-indene resin.	
Cresyl diphenyl phosphate.	
Cumene hydroperoxide.	
Cyanoguanidine.	
Cyclized rubber as identified in § 176.170(b)(2) of this chapter.	
Cyclohexane.	
1,4-Cyclohexanedimethanoldibenzoate (CAS Reg. No. 35541–81–2).	
Cyclohexanol.	
Cyclohexanone resin.	
Cyclohexanone-formaldehyde condensate.	
<i>N</i> -Cyclohexyl <i>p</i> -toluene sulfonamide.	
( $\eta^5$ -Cyclopentadienyl)-( $\eta^6$ -isopropylbenzene)iron(II) hexafluorophosphate (CAS Reg. No. 32760–80–8).	For use only as a photoinitiator.
Damar.	
Defoaming agents as described in § 176.210 of this chapter.	
Dehydroacetic acid .....	
Diacetone alcohol.	
Diacetyl peroxide.	

Substances	Limitations
<i>N,N'</i> -Dialkoyl-4,4'-diaminodiphenylmethane mixtures where; the alkoyl groups are derived from marine fatty acids (C <sub>12</sub> -C <sub>24</sub> ).	
2,5-Di- <i>tert</i> -amylhydroquinone.	
Diamines derived from dimerized vegetable oil acids.	
Diaryl- <i>p</i> -phenylenediamine, where the aryl group may be phenyl, tolyl, or xylol.	
1,2-Dibromo-2,4-dicyanobutane (CAS Registry No. 3569-65-7) .....	For use as a preservative only.
2,2-Dibromo-3-nitropropionamide (CAS Reg. No. 10222-01-2). ....	For use as a preservative only.
Di(butoxyethyl) phthalate.	
2,5-Di- <i>tert</i> -butylhydroquinone.	
Dibutyl maleate.	
2,6-Di- <i>tert</i> -butyl-4-methylphenol .....	For use as preservative only.
Di(C <sub>7</sub> , C <sub>9</sub> -alkyl)adipate.	
Dibutyl phthalate.	
Dibutyl sebacate.	
Dibutyltin dilaurate for use only as a catalyst for polyurethane resins.	
1,2-Dichloroethylene (mixed isomers).	
Dicumyl peroxide.	
Dicyclohexyl phthalate.	
Diethanolamine.	
Diethanolamine condensed with animal or vegetable fatty acids.	
Diethylamine.	
Diethylene glycol.	
Diethylene glycol adipic acid copolymer.	
Diethylene glycol dibenzoate.	
Diethylene glycol hydrogenated tallowate monoester.	
Diethylene glycol laurate.	
Diethylene glycol monobutyl ether.	
Diethylene glycol monobutyl ether acetate.	
Diethylene glycol monoethyl ether.	
Diethylene glycol monoethyl ether acetate.	
Diethylene glycol monomethyl ether.	
Diethylene glycol monooleate.	
Diethylene glycol monophenyl ether.	
Diethylene glycol copolymer of adipic acid and phthalic anhydride.	
Di(2-ethylhexyl) adipate.	
Di(2-ethylhexyl)hexahydrophthalate.	
Di(2-ethylhexyl)phthalate.	
Diethyl oxalate.	
Diethyl phthalate.	
Dihexyl phthalate.	
Dihydroabietylphthalate.	
Di(2-hydroxy-5- <i>tert</i> -butylphenyl) sulfide.	
2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane (dichlorophene).	
4,5-Dihydroxy-2-imidazolidinone.	
4-(Diiodomethylsulfonyl) toluene CA Registry No.: 20018-09-01 .....	For use as an antifungal preservative only.
Diisobutyl adipate.	
Diisobutyl ketone.	
Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.	
Diisobutyl phthalate.	
Diisodecyl adipate.	
Diisodecyl phthalate.	
Diisooctyl phthalate.	
Diisopropylbenzene hydroperoxide.	
<i>N,N</i> -Dimethylcyclohexylamine dibutylidithiocarbamate.	
Dimethyl formamide.	
Dimethyl hexynol.	
2,2-Dimethyl-1,3-propanediol dibenzoate.	
Dimethyl octynediol.	
<i>N</i> -(1,1-dimethyl-3-oxobutyl) acrylamide.	
Dimethyl phthalate.	
3,5-Dimethyl-1,3,5,2 <i>H</i> -tetrahydrothiadiazine-2-thione .....	For use as preservative only.
Di-β-naphthyl- <i>p</i> -phenylenediamine.	
4,6-Dinonyl- <i>o</i> -cresol.	
Dinonylphenol.	
Di- <i>n</i> -octyldecyl adipate.	
Diocetylphenylamine.	
Diocetylphthalate.	
Diocetylsebacate.	
Dioxane.	
Dipentaerythritol pentastearate.	
Dipentamethylene-thiuram-tetrasulfide.	
Dipentene .....	
Dipentene resins.	

Substances	Limitations
<p>Dipentene-<i>beta</i>-pinene-styrene resins.  Dipentene-styrene resin (CAS Registry No. 64536-06-7).  Diphenyl-2-ethylhexyl phosphate.  Diphenyl, hydrogen ated.  <i>N,N</i>-Diphenyl-<i>p</i>-phenylenediamine.  Diphenyl phthalate.  1,3-Diphenyl-2-thiourea.  Dipropylene glycol.  Dipropylene glycol dibenzoate.  Dipropylene glycol monomethyl ether.  Dipropylene glycol copolymer of adipic acid and phthalic anhydride.  Disodium cyanodithioimidocarbonate.  Disodium 4-isodecyl sulfosuccinate (CAS Reg. No. 37294-49-8).  <i>N,N</i>-Distearoylethylenediamine.  Distearyl thiodipropionate.  3,5-Di-<i>tert</i>-butyl-4-hydroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-<i>s</i>-triazine-2,4,6(1<i>H</i>, 3<i>H</i>, 5<i>H</i>)-trione.  4,4'-Dithiodimorpholine.  <i>n</i>-Dodecylmercaptan.  <i>tert</i>-Dodecylmercaptan.  Dodecylphenoxybenzene-disulfonic acid and/or its calcium, magnesium, and sodium salts.  Elemi gum.  Epichlorohydrin-4,4'-isopropylidenediphenol resin.  Epichlorohydrin-4,4'-<i>sec</i>-butylidenediphenol resin.  Epichlorohydrin-4,4'-isopropylidene-di-<i>o</i>-cresol resin.  Epichlorohydrin-phenolformaldehyde resin.  Erucamide (erucylamide).  Ethanalamine.  Ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 (CAS Reg. No. 97953-22-5).  Ethoxypropanol butyl ether.  Ethyl alcohol (ethanol).  5-Ethyl-1,3-diglycidyl-5-methylhydantoin (CAS Reg. No. 15336-82-0).  Ethylene-acrylic acid-carbon monoxide copolymer (CAS Reg. No. 97756-27-9).  Ethylene-acrylic acid copolymer, partial sodium salt containing no more than 20 percent acrylic acid by weight, and no more than 16 percent of the acrylic acid as the sodium salt (CAS Reg. No. 25750-82-7).  Ethylenediamine.  Ethylenediaminetetra-acetic acid, calcium, ferric, potassium, or sodium salts, single or mixed.  Ethylene dichloride.  Ethylene glycol.  Ethylene glycol monobutyl ether.  Ethylene glycol monobutyl ether acetate.  Ethylene glycol monoethyl ether.  Ethylene glycol monoethyl ether acetate.  Ethylene glycol monoethyl ether ricinoleate.  Ethylene glycol monomethyl ether.  Ethylene glycol monophenyl ether.  Ethylene-carbon monoxide copolymer (CAS Reg. No. 25052-62-4) containing not more than 30 weight percent of the units derived from carbon monoxide.  Ethylene-maleic anhydride copolymer, ammonium or potassium salt.  Ethylene-methacrylic acid copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.  Ethylene-methacrylic acid-vinyl acetate copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.  Ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene (CAS Reg. No. 26221-73-8).  Ethylene-propylene-dicyclopentadiene copolymer rubber.  Ethylene, propylene, 1,4-hexadiene and 2,5-norbornadiene tetrapolymer.  Ethylene-vinyl acetate carbon monoxide terpolymer (CAS Registry No. 26337-35-9) containing not more than 15 weight percent of units derived from carbon monoxide.  2,2'-Ethylenedibis(4,6-di-<i>tert</i>-butylphenol) (CAS Reg. No. 35958-30-6).  Ethyl-<i>p</i>-hydroxybenzoate .....  Ethyl hydroxyethylcellulose.  Ethyl lactate.  2,2'-Ethylenedibis(4,6-di-<i>tert</i>-butylphenyl)fluorophosphonite (CAS Reg. No. 118337-09-0).  Ethyl phthalyl ethyl glycolate.</p>	<p>For use as antioxidant only.</p> <p>For use as preservative only.</p> <p>For use as an antioxidant and/or stabilizer only.</p>

Substances	Limitations
Ethyl- <i>p</i> -toluene sulfonamide .....	
Fats and oils derived from animal or vegetable sources, and the hydrogenated, sulfated, or sulfonated forms of such fats and oils.	
Fatty acids derived from animal or vegetable fats and oils; and salts of such acids, single or mixed, as follows:	
Aluminum.	
Ammonium.	
Calcium.	
Magnesium.	
Potassium.	
Sodium.	
Zinc.	
Ferric chloride.	
Fluosilicic acid (hydrofluosilicic acid) .....	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Formaldehyde.	
Formaldehyde <i>o</i> - and <i>p</i> -toluene sulfonamide.	
Formamide.	
Fumaratochromium (III) nitrate.	
Furfural.	
Furfuryl alcohol.	
Fumaric acid.	
<i>gamma</i> -Aminopropyltrimethoxysilane (CAS Reg. No. 13822–56–5).	
Glutaraldehyde.	
Glycerides, di- and monoesters.	
Glycerol polyoxypropylene triol, minimum average molecular weight 250 (CAS Reg. No. 25791–96–2).	For use only in the preparation of polyester and polyurethane resins in adhesives.
Glyceryl borate (glycol boriborate resin).	
Glyceryl ester of damar, copal, elemi, and sandarac.	
Glyceryl monobutyl ricinoleate.	
Glyceryl monohydroxy stearate.	
Glyceryl monohydroxy tallowate.	
Glyceryl polyoxypropylene triol (average molecular weight 1,000).	
Glyceryl tribenzoate.	
Glycol diacetate.	
Glyoxal.	
Heptane.	
Hexamethylenetetramine.	
Hexane.	
Hexanetriols.	
Hexylene glycol.	
Hydroabietyl alcohol.	
Hydrocarbon resins (produced by polymerization of mixtures of mono- and di-unsaturated hydrocarbons of the aliphatic, alicyclic, and monobenzenoid type derived both from cracked petroleum and terpene stocks) (CAS Reg. No. 68239–99–6).	
Hydrocarbon resins (produced by the polymerization of styrene and <i>alpha</i> -methyl styrene), hydrogenated (CAS Reg. No. 68441–37–2).	
Hydrofluoric acid .....	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Hydrogen peroxide.	
Hydrogenated dipentene resin (CAS Reg. No. 106168–39–2).	
Hydrogenated dipentene-styrene copolymer resin (CAS Reg. No. 106168–36–9).	
Hydrogenated- <i>beta</i> -pinene- <i>alpha</i> -pinene-dipentene copolymer resin (CAS Reg. No. 106168–37–0).	
<i>a</i> -Hydro- <i>omega</i> -hydroxypoly-(oxytetramethylene) .....	For use only in the preparation of polyurethane resins.
Hydroquinone.	
Hydroquinone monobenzyl ether.	
Hydroquinone monoethyl ether.	
2(2'-Hydroxy-3',5'-di- <i>tert</i> -amylphenyl) benzotriazole.	
Hydroxyacetic acid.	
7-Hydroxycoumarin.	
Hydroxyethylcellulose.	
2-Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone(CAS Reg. No. 106797–53–9).	For use only as a photoinitiator at a level not to exceed 5 percent by weight of the adhesive.
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2 alkyl (C <sub>6</sub> -C <sub>17</sub> ) imidazolium chloride.	
Hydroxyethyldiethylenetriamine.	

**§ 175.105**

165



Substances	Limitations
<p>Methyl ricinoleate.</p> <p>Methyl salicylate.</p> <p><i>a</i>-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 <i>a</i> methylstyrene to 3 vinyltoluene).</p> <p>Methyl tallowate.</p> <p>Mineral oil.</p> <p>Monochloroacetic acid.</p> <p>Monooctyldiphenylamine.</p> <p>Montan wax.</p> <p>Morpholine.</p> <p>Myristic acid-chromic chloride complex.</p> <p>Myristyl alcohol.</p> <p>Naphtha.</p> <p>Naphthalene, monosulfonated.</p> <p>Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.</p> <p><math>\alpha</math>-Naphthylamine.</p> <p><math>\alpha, \alpha', \alpha'', \alpha'''</math>-Neopentane tetrayltetrakis [<i>omega</i>-hydroxypoly (oxypropylene) (1–2 moles)], average molecular weight 400.</p> <p>Nitric acid.</p> <p><math>\mu</math>-Nitrobiphenyl.</p> <p>Nitrocellulose.</p> <p>2-Nitropropane.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 6–9 moles or 50 moles.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of <i>p</i>-nonylphenol (nonyl group is a propylene trimer isomer) with an average of 1–40 moles of ethylene oxide.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) sulfate, ammonium salt: the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles.</p> <p><i>endo-cis</i>-5-Norbornene-2,3-dicarboxylic anhydride.</p> <p><math>\alpha</math>-<i>cis</i>-9-Octadecenyl-<i>omega</i>-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.</p> <p>Octadecyl 3,5-di-<i>tert</i>-butyl-4-hydroxyhydrocinnamate.</p> <p>Octyl alcohol.</p> <p>Octyldecyl phthalate.</p> <p>Octylphenol.</p> <p>Octylphenoxyethanols.</p> <p>Octylphenoxypropoxy-polypropoxyethanol (13 moles of ethylene oxide and propylene oxide).</p> <p>Odorless light petroleum hydrocarbons.</p> <p>Oleamide (oleic acid amide).</p> <p>Oleic acid, sulfated.</p> <p>2,2'-Oxamidobis[ethyl 3-(3,5-di-<i>tert</i>-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331–94–1).</p> <p>Oxazoline.</p> <p><math>\alpha</math>-(oxiranylmethyl)-<math>\omega</math>-(oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], (alternative name: epichlorohydrin-polypropylene glycol) (CAS Reg. No. 26142–30–3).</p> <p>2,2'-[oxybis(methyl-2,1-ethanediyl)-oxymethylene]bisoxirane, (alternative name: epichlorohydrin-dipropylene glycol) (CAS Reg. No. 41638–13–5).</p> <p><i>n</i>-Oxydiethylene-benzothiazole.</p> <p>Palmitamide (palmitic acid amide).</p> <p>Paraffin (C<sub>12</sub>-C<sub>20</sub>) sulfonate.</p> <p>Paraformaldehyde.</p> <p>Pentachlorophenol.</p> <p>Pentaerythritol ester of maleic anhydride.</p> <p>Pentaerythritol monostearate .....</p> <p>Pentaerythritol tetrabenzoate [CAS Registry No. 4196–86–5].</p> <p>Pentaerythritol tetrastearate.</p> <p>2,4-Pentanedione.</p> <p>Pentasodium diethylenetriaminepentaacetate (CAS Reg. No. 140–01–2).</p> <p>Perchloroethylene.</p> <p>Petrolatum.</p> <p>Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated.</p> <p>Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).</p>	<p>For use as a reactant in the preparation of epoxy-based resins.</p> <p>For use as a reactant in the preparation of epoxy-based resins.</p> <p>For use as preservative only.</p>

Substances	Limitations
Petroleum hydrocarbon resins (produced by the homo-and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks).	
Phenol .....	For use as preservative only.
Phenol-coumarone-indene resin.	
Phenolic resins as described in § 175.300(b)(3)(vi).	
Phenothiazine .....	For use only as polymerization-control agent.
Phenyl-β-naphthylamine (free of β-naphthylamine).	
o-Phenylphenol .....	For use as preservative only.
o-Phthalic acid.	
Pimaric acid .....	
Pine oil.	
Piperazine.	
Piperidinium pentamethylenedithiocarbamate.	
Poly(acrylamide-[2-acrylamide-2-methylpropylsulfonate]-dimethylidialyl ammonium chloride) sodium salt (CAS Reg. No. 72275-68-4).	
Polyamides derived from reaction of one or more of the following acids with one or more of the following amines:	
Acids:	
Azelaic acid.	
Dimerized vegetable oil acids.	
Amines:	
Bis(hexamethylene) triamine and higher homologues.	
Diethylenetriamine.	
Diphenylamine.	
Ethylenediamine.	
Hexamethylenediamine.	
Poly(oxypropylene)diamine (weight average molecular weight 2010) (CAS Reg. No. 9046-10-0).	
Poly(oxypropylene)diamine (weight average molecular weight 440) (CAS Reg. No. 9046-10-0).	
Tetraethylenepentamine.	
Triethylenetetramine.	
Polybutene, hydrogenated.	
Polybutylene glycol (molecular weight 1,000).	
Poly [2(diethylamino) ethyl methacrylate] phosphate.	
Polyester of adipic acid, phthalic acid, and propylene glycol, terminated with butyl alcohol.	
Polyester of diglycolic acid and propylene glycol containing ethylene glycol monobutyl ether as a chain stopper.	
Polyester resins (including alkyd type), as the basic polymer, formed as esters when one or more of the following acids are made to react with one or more of the following alcohols:	
Acids:	
Azelaic acid.	
Dimethyl 1,4-cyclohexanedicarboxylate (CAS Reg. No. 94-60-0).	
Dimethyl-5-sulfoisophthalic acid (CAS Reg. No. 50975-82-1) and/or its sodium salt (CAS Reg. No. 3965-55-7).	
Polybasic and monobasic acids identified in § 175.300(b)(3)(vii)(a) and (b).	
5-sulfo-1,3-benzenedicarboxylic acid, monosodium salt (CAS Reg. No. 6362-79-4).	
Tetrahydrophthalic acid.	
Alcohols:	
1,4-Cyclohexanedimethanol.	
2,2-Dimethyl-1,3-propanediol.	
1,6-Hexanediol (CAS Reg. No. 629-11-8).	
Polyhydric and monohydric alcohols identified in § 175.300(b)(3)(vii)(c) and (d).	
Polyethylenedipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.	
Polyethylene glycol (molecular weight 200-6,000).	
Polyethylene glycol mono-isotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413-26-6).	
Polyethyleneglycol alkyl(C <sub>10</sub> -C <sub>12</sub> )ether sulfosuccinate, disodium salt (CAS Reg. No. 68954-91-6).	
Polyethylene, oxidized.	
Polyethylene resins, carboxyl modified, identified in § 177.1600 of this chapter.	
Polyethylenimine.	
Polyethylenimine-epichlorohydrin resins.	For use only in the preparation of polyurethan resins.

Substances	Limitations
<p>Poly(ethyloxazoline) (CAS Reg. No. 25805-17-8).</p> <p>Polyisoprene.</p> <p>Polymeric esters of polyhydric alcohols and polycarboxylic acids prepared from glycerin and phthalic anhydride and modified with benzoic acid, castor oil, coconut oil, linseed oil, rosin, soybean oil, styrene, and vinyl toluene.</p> <p>Polymers: Homopolymers and copolymers of the following monomers:.</p> <p>Acrylamide.</p> <p>Acrylic acid.</p> <p>Acrylonitrile.</p> <p>Allylmethacrylate (CAS Reg. No. 00096–05–09).</p> <p>Butadiene.</p> <p>Butene.</p> <p><i>N</i>-<i>tert</i>-Butylacrylamide.</p> <p>Butyl acrylate.</p> <p>1,3-Butylene glycol dimethacrylate.</p> <p>Butyl methacrylate.</p> <p>Crotonic acid.</p> <p>Decyl acrylate.</p> <p>Diallyl fumarate.</p> <p>Diallyl maleate.</p> <p>Diallyl phthalate.</p> <p>Dibutyl fumarate.</p> <p>Dibutyl itaconate.</p> <p>Dibutyl maleate.</p> <p>Di(2-ethylhexyl) maleate.</p> <p>Dimethyl-<math>\alpha</math>-methylstyrene.</p> <p>Dioctyl fumarate.</p> <p>Dioctyl maleate.</p> <p>Divinylbenzene.</p> <p>Ethyl acrylate.</p> <p>Ethylene.</p> <p>Ethylene cyanohydrin.</p> <p>2-Ethylhexyl acrylate.</p> <p>Ethyl methacrylate.</p> <p>Fatty acids, C<sub>10-13</sub>-branched, vinyl esters (CAS Reg. No. 184785–38–4).</p> <p>Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl hexyl, heptyl and octyl esters.</p> <p>Glycidyl methacrylate.</p> <p>1-Hexene (CAS Reg. No. 592–41–6).</p> <p>2-Hydroxyethyl acrylate.</p> <p>2-Hydroxyethyl methacrylate.</p> <p>2-Hydroxypropyl methacrylate.</p> <p>Isobutyl acrylate.</p> <p>Isobutylene.</p> <p>Itaconic acid.</p> <p>Maleic acid, diester with 2-hydroxyethanesulfonic acid, sodium salt.</p> <p>Maleic anhydride.</p> <p>Methacrylic acid.</p> <p>Methyl acrylate.</p> <p><i>N,N'</i>-Methylenebisacrylamide.</p> <p>Methyl methacrylate.</p> <p><i>N</i>-Methylolacrylamide.</p> <p>Methyl styrene.</p> <p>-Methyl styrene.</p> <p>Monoethyl maleate.</p> <p>Monomethyl maleate.</p> <p>Mono (2-ethylhexyl) maleate.</p> <p>5-Norbornene-2,3-dicarboxylic acid, mono-<i>n</i>-butyl ester.</p> <p>1-Octene (CAS Reg. No. 111–66–0).</p> <p>Propyl acrylate.</p> <p>Propylene.</p> <p>Styrene.</p> <p>Triallyl cyanurate.</p> <p>Vinyl acetate.</p> <p>Vinyl alcohol (from alcoholysis or hydrolysis of vinyl acetate units).</p> <p>Vinyl butyrate.</p> <p>Vinyl chloride.</p> <p>Vinyl crotonate.</p> <p>Vinyl ethyl ether.</p> <p>Vinyl hexoate.</p> <p>Vinylidene chloride.</p> <p>Vinyl methyl ether.</p>	

Substances	Limitations
<p>Vinyl pelargonate.  Vinyl propionate.  Vinyl pyrrolidone.  Vinyl stearate.  Polyoxyalkylated-phenolic resin (phenolic resin obtained from formaldehyde plus butyl- and/or amylphenols, oxyalkylated with ethylene oxide and/or propylene oxide).  Poly(oxyacryloyl) diols and triols (minimum molecular weight 500).  Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt.  Polyoxyethylene (20 mol)—anhydrous lanolin adduct.  Polyoxyethylene (molecular weight 200) dibenzoate.  Polyoxyethylene (molecular weight 200–600) esters of fatty acids derived from animal or vegetable fats and oils (including tall oil).  Polyoxyethylene (15 moles) ester of rosin.  Polyoxyethylene (4–5 moles) ether of phenol.  Polyoxyethylene (25 moles)—glycerol adduct.  Polyoxyethylene (40 moles) stearate.  Polyoxyethylene (5–15 moles) tridecyl alcohol.  Polyoxypropylene (3 moles) tridecyl alcohol sulfate.  Polyoxypropylene (20 moles) butyl ether.  Polyoxypropylene (40 moles) butyl ether.  Polyoxypropylene (20 moles) oleate butyl ether.  Polyoxypropylene-polyoxyethylene condensate (minimum molecular weight 1,900).  Polypropylene glycol (minimum molecular weight 150).  Polypropylene glycol (3–4 moles) triether with 2-ethyl-2-(hydroxymethyl)-1,3-propane-diol, average molecular weight 730.  Polypropylene glycol dibenzoate (CAS Reg. No. 72245–46–6) .....</p> <p>Polypropylene, noncrystalline.  Polysiloxanes:  Diethyl polysiloxane.  Dihydrogen polysiloxane.  Dimethyl polysiloxane.  Diphenyl polysiloxane.  Ethyl hydrogen polysiloxane.  Ethyl phenyl polysiloxane.  Methyl ethyl polysiloxane.  Methyl hydrogen polysiloxane.  Methyl phenyl polysiloxane.  Phenyl hydrogen polysiloxane.  Polysorbate 60.  Polysorbate 80.  Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate).  Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate).  Poly[styrene-co-sodium maleate-co-<math>\alpha</math>-(<i>p</i>-nonyl-phenyl)-<i>omega</i>-(<i>p</i>-vinyl-benzyl)poly(oxyethylene)] terpolymer.  Polytetrafluoroethylene..  Polyurethane resins produced by: (1) reacting diisocyanates with one or more of the polyols or polyesters named in this paragraph, or (2) reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this paragraph with one or more of the polyamines named in this paragraph, or (3) reacting toluene diisocyanate or 4,4' methylenebis(cyclohexylisocyanate) (CAS Reg. No. 5124–30–1) with: (i) one or more of the polyols or polyesters named in this paragraph and with either <i>N</i>-methyl-diethanolamine (CAS Reg. No. 105–59–9) and dimethyl sulfate (CAS Reg. No. 77–78–1) or dimethylolpropionic acid (CAS Reg. No. 4767–03–7) and triethylamine (CAS Reg. No. 121–44–8), or (ii) a fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol, triethylamine (CAS Reg. No. 107–15–3), and ethylenediamine (CAS Reg. No. 121–44–8), or (4) reacting <i>meta</i>-tetramethylxylene diisocyanate (CAS Reg. No. 2778–42–9) with one or more of the polyols and polyesters listed in this paragraph and with dimethylolpropionic acid (CAS Reg. No. 4767–03–7) and triethylamine (CAS Reg. No. 121–44–8), <i>N</i>-methyl-diethanolamine (CAS Reg. No. 105–59–9), 2-dimethylaminoethanol (CAS Reg. No. 108–01–0), 2-dimethylamino-2-methyl-1-propanol (CAS Reg. No. 7005–47–2), and/or 2-amino-2-methyl-1-propanol (CAS Reg. No. 124–68–5).  Polyvinyl alcohol modified so as to contain not more than 3 weight percent of comonomer units derived from 1-alkenes having 12 to 20 carbon atoms.  Polyvinyl butyral.  Polyvinyl formal.</p>	<p>For use as a plasticizer at levels not to exceed 20 percent by weight of the finished adhesive.</p>

Substances	Limitations
Potassium ferricyanide .....	For use only as polymerization-control agent.
Potassium <i>N</i> -methylthiocarbamate.	
Potassium pentachlorophenate .....	For use as preservative only.
Potassium permanganate.	
Potassium persulfate.	
Potassium phosphates (mono-, di-, tribasic).	
Potassium tripolyphosphate.	
$\alpha$ , $\alpha'$ , $\alpha''$ -1,2,3-Propanetriyltris [ <i>omega</i> -(2,3-epoxypropoxy) poly (oxypropylene) (24 moles)].	
$\beta$ -Propiolactone.	
Propyl alcohol (propanol).	
Propylene carbonate.	
Propylene glycol and <i>p-p'</i> -isopropylidenediphenol diether.	
Propylene glycol dibenzoate (CAS Reg. No. 19224–26–1) .....	For use as a plasticizer at levels not to exceed 20 percent by weight of the finished adhesive.
Propylene glycol esters of coconut fatty acids.	
Propylene glycol monolaurate.	
Propylene glycol monomethyl ether.	
Propylene glycol monostearate.	
$\alpha$ , $\alpha'$ , $\alpha''$ -[Propylidynetris (methylene)] tris [ <i>omega</i> -hydroxypoly (oxypropylene) (1.5 moles minimum)], minimum molecular weight 400.	
Quaternary ammonium chloride (hexadecyl, octadecyl derivative) .....	For use as preservative only.
Rosin (wood, gum, and tall oil rosin), rosin dimers, decarboxylated rosin (including rosin oil, disproportionated rosin, and these substances as modified by one or more of the following reactants:	
Alkyl (C <sub>1</sub> -C <sub>9</sub> ) phenolformaldehyde.	
Ammonia.	
Ammonium caseinate- <i>p</i> -Cyclohexylphenolformaldehyde.	
Diethylene glycol.	
Dipentaerythritol.	
Ethylene glycol.	
Formaldehyde.	
Fumaric acid.	
Glycerin.	
Hydrogen.	
Isophthalic acid.	
4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).	
4,4'-Isopropylidenediphenol-formaldehyde.	
Maleic anhydride.	
Methyl alcohol.	
Pentaerythritol.	
Phthalic anhydride.	
Polyethylene glycol.	
Phenol-formaldehyde.	
Phenyl $\mu$ -cresol-formaldehyde.	
<i>p</i> -Phenylphenol-formaldehyde.	
Sulfuric acid.	
Triethylene glycol.	
Xylenol-formaldehyde.	
Rosin salts (salts of wood, gum, and tall oil rosin, and the dimers thereof, decarboxylated rosin disproportionated rosin, hydrogenated rosin):	
Aluminum.	
Ammonium.	
Calcium.	
Magnesium.	
Potassium.	
Sodium.	
Zinc.	
Rosin, gasoline-insoluble fraction.	
Rubber hydrochloride polymer.	
Rubber latex, natural.	
Salicylic acid .....	For use as preservative only.
Sandarac.	
Sebacic acid.	
Shellac.	
Silicon dioxide as defined in § 172.480(a) of this chapter.	
Sodium alkyl (C <sub>2</sub> -C <sub>13.5</sub> aliphatic) benzenesulfonate.	
Sodium aluminum pyrophosphate.	
Sodium aluminum sulfate.	
Sodium bisulfate.	
Sodium calcium silicate.	
Sodium capryl polyphosphate.	
Sodium carboxymethylcellulose.	
Sodium chlorate.	

**§ 175.105**

171

Substances	Limitations
Sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether disodium salt (alcohol moiety produced by condensation of 1 mole of <i>n</i> -dodecyl alcohol and an average of 5–6 moles of ethylene oxide, Chemical Abstracts Service Registry No. 039354–45–5).	
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole of nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).	
Sulfur.	
Synthetic primary linear aliphatic alcohols whose weight average molecular weight is greater than 400 (CAS Reg. No. 71750–71–5).	
Synthetic wax polymer as described in § 176.170(a)(5) of this chapter.	
Tall oil.	
Tall oil fatty acids, linoleic and oleic.	
Tall oil fatty acid methyl ester.	
Tall oil, methyl ester.	
Tall oil pitch.	
Tall oil soaps.	
Tallow alcohol (hydrogenated).	
Tallow amine, secondary (hexadecyl, octadecyl), of hard tallow.	
Tallow, blown (oxidized).	
Tallow, propylene glycol ester.	
Terpene resins ( $\alpha$ - and $\beta$ -pinene) homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.	
Terphenyl.	
Terphenyl, hydrogenated.	
Terpineol.	
Tetraethylene pentamine.	
Tetraethylthiuram disulfide.	
Tetrahydrofuran.	
Tetrahydrofurfuryl alcohol.	
Tetra-isopropyl titanate.	
Terakis[methylene (3,5-di- <i>tert</i> -butyl-4-hydroxy-hydro-cinnamate)] methane.	
A-[ <i>p</i> -(1,1,3,3-Tetramethylbutyl) phenyl]- <i>omega</i> -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i> -(1,1,3,3-tetramethylbutyl) phenol with an average of 1–40 moles of ethylene oxide.	
A-[ <i>p</i> -(1,1,3,3-Tetramethylbutyl) phenyl]- <i>omega</i> -hydroxy-poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles.	
Tetramethyl decanediol.	
Tetramethyl decynediol.	
Tetramethyl decynediol plus 1–30 moles of ethylene oxide.	
Tetramethylthiuram monosulfide.	
Tetrasodium <i>N</i> -(1,2-dicarboxyethyl)- <i>N</i> -octadecylsulfosuccinamate.	
4,4'-Thiobis-6- <i>tert</i> -butyl- <i>m</i> -cresol.	
Thiodiethylene-bis(3,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamate).	
2,2'-(2,5-Thiophenediyl) bis[5- <i>tert</i> -butylbenzoxazole].	
Thiram.	
Thymol .....	For use as preservative only.
Titanium dioxide.	
Titanium dioxide-barium sulfate.	
Titanium dioxide-calcium sulfate.	
Titanium dioxide-magnesium silicate.	
Toluene.	
Toluene 2,4-diisocyanate.	
Toluene 2,6-diisocyanate.	
<i>o</i> - and <i>p</i> -Toluene ethyl sulfonamide.	
<i>o</i> - and <i>p</i> -Toluene sulfonamide.	
<i>p</i> -Toluene sulfonic acid.	
<i>p</i> -( <i>p</i> '-Toluene-sulfonylamide)-diphenylamide.	
Triazine-formaldehyde resins as described in § 175.300(b)(3)(xiii).	
Tributoxyethyl phosphate.	
Tributylcitrate.	
Tri- <i>tert</i> -butyl- <i>p</i> -phenyl phenol .....	For use as preservative only.
Tributyl phosphate.	
Tributyltin chloride complex of ethylene oxide condensate of dehydroabietylamine.	For use as preservative only.
Tri- <i>n</i> -butyltin acetate .....	For use as preservative only.
Tri- <i>n</i> -butyltin neodecanoate .....	Do.
1,1,1-Trichloroethane.	
1,1,2-Trichloroethane.	
Trichloroethylene.	

**§ 175.125**

Substances	Limitations
Tri-β-chloroethylphosphate. Tridecyl alcohol. Triethanolamine. 3-(Triethoxysilyl) propylamine. Triethylene glycol. Triethylene glycol dibenzoate. Triethylene glycol di(2-ethylhexoate). Triethylene glycol polyester of benzoic acid and phthalic acid. Triethylhexyl phosphate. Triethylphosphate. 2,4,5-Trihydroxy butyrophenone. Triisopropanolamine. Trimethylol propane. 2,2,4-Trimethylpentanediol-1,3-diisobutylate. Trimeric aromatic amine resin from diphenylamine and acetone of molecular weight approximately 500. Tri(nonylphenyl) phosphite-formaldehyde resins .....	As identified in § 177.2600(c)(4)(iii) of this chapter. For use only as a stabilizer.
Triphenylphosphate. Tripropylene glycol monomethyl ether. 1,3,5-Tris (3,5-di- <i>tert</i> -butyl-4-hydroxy-benzyl)-triazine-2,4,6 (1H,3H,5H)-trione. Tris ( <i>p</i> -tertiary butyl phenyl) phosphate. Tris(2-methyl-4-hydroxy-5- <i>tert</i> -butyl-phenyl)butane. Trisodium <i>N</i> -hydroxyethylethylenediaminetriacetate (CAS Reg. No. 139–89–9). Turpentine. Urea-formaldehyde resins as described in § 175.300(b)(3)(xii). Vegetable oil, sulfonated or sulfated, potassium salt. Vinyl acetate-maleic anhydride copolymer, sodium salt. Waxes, petroleum. Wax, petroleum, chlorinated (40% to 70% chlorine). Waxes, synthetic paraffin (Fischer-Tropsch process). 3-(2-Xenolyl)-1,2-epoxypropane. Xylene. Xylene (or toluene) alkylated with dicyclopentadiene. Zein. Zinc acetate. Zinc ammonium chloride. Zinc dibenzyl dithiocarbamate. Zinc dibutyldithiocarbamate. Zinc diethyldithiocarbamate. Zinc di(2-ethylhexoate). Zinc formaldehyde sulfoxylate. Zinc naphthenate and dehydroabietylamine mixture. Zinc nitrate. Zinc orthophosphate. Zinc resinate. Zinc sulfide. Zineb (zinc ethylenebis-dithiocarbamate). Ziram (zinc dimethyldithiocarbamate).	

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §175.105, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

tact surface of labels and/or tapes applied to poultry, dry food, and processed, frozen, dried, or partially dehydrated fruits or vegetables.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with a prior sanction or approval.



## § 175.210

(3) Color additives listed for use in or on food in parts 73 and 74 of this chapter.

(4) Substances identified in § 172.615 of this chapter other than substances used in accordance with paragraph (a)(2) of this section.

(5) Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a) of this chapter.

(6) 4-[[4, 6-Bis(octylthio)-s-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4) as an antioxidant/stabilizer at a level not to exceed 1.5 percent by weight of the finished pressure-sensitive adhesive.

(7) 2,2'-(2,5-Thiophenediyl)-bis(5-*tert*-butylbenzoxazole) (CAS Reg. No. 7128-64-5) as an optical brightener at a level not to exceed 0.05 percent by weight of the finished pressure-sensitive adhesive.

(8) 2-Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone (CAS Reg. No. 106797-53-9) as a photoinitiator at a level not to exceed 5 percent by weight of the pressure-sensitive adhesive.

(9) Butanedioic acid, sulfo-1,4-di-(C<sub>9</sub>-C<sub>11</sub> alkyl) ester, ammonium salt (also known as butanedioic acid sulfo-1, 4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]) as a surface active agent at a level not to exceed 3.0 percent by weight of the finished pressure-sensitive adhesive.

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

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

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

BHA.

BHT.

Butadiene-acrylonitrile copolymer.

Butadiene-acrylonitrile-styrene copolymer.

Butadiene-styrene copolymer.

Butyl rubber.

Butylated reaction product of *p*-cresol and dicyclopentadiene produced by reacting *p*-

## 21 CFR Ch. I (4–1–16 Edition)

cresol and dicyclopentadiene in an approximate mole ratio of 1.5 to 1.0, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent, for use at levels not to exceed 1.0 percent by weight of the adhesive formulation.

Chlorinated natural rubber.

Isobutylene-styrene copolymer.

Petrolatum.

Polybutene-1.

Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.

Polyisobutylene.

*cis*-1,4-Polyisoprene.

Polystyrene.

Propyl gallate.

Rapeseed oil, vulcanized.

Rosins and rosin derivatives as provided in § 178.3870 of this chapter.

Rubber hydrochloride.

Rubber (natural latex solids or crepe, smoked or unsmoked).

Terpene resins ( $\alpha$ - and  $\beta$ -pinene), homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.

Tetrasodium ethylenediaminetetraacetate.

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

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

[42 FR 14534, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 48 FR 15617, Apr. 12, 1983; 63 FR 3464, Jan. 23, 1998; 63 FR 51528, Sept. 28, 1998; 64 FR 48291, Sept. 3, 1999]

## Subpart C—Substances for Use as Components of Coatings

### § 175.210 Acrylate ester copolymer coating.

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

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

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the

## Food and Drug Administration, HHS

## § 175.250

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

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

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

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

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

### § 175.230 Hot-melt strippable food coatings.

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

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

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

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides .....	Complying with 172.828 of this chapter.
Cellulose acetate butyrate.	

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

### § 175.250 Paraffin (synthetic).

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

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and may be further treated by percolation through activated charcoal. This mixture can be fractionated into its components by a solvent separation method, using synthetic isoparaffinic petroleum hydrocarbons complying with § 178.3530 of this chapter.

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

(1) *Congealing point.* There is no specification for the congealing point of synthetic paraffin components, except those components that have a congealing point below 50 °C when used in contact with food Types III, IVA, V, VIIA, and IX identified in table 1 of § 176.170(c) of this chapter and under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter shall be limited to a concentration not exceeding 15 percent by weight of the finished coating. The congealing point shall be determined by ASTM method D938-71 (Reapproved 1981), "Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-

## § 175.260

## 21 CFR Ch. I (4–1–16 Edition)

2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

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

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

(c) The provisions of this section are not applicable to synthetic paraffin used in food-packaging adhesives complying with § 175.105.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 51 FR 47010, Dec. 30, 1986; 60 FR 39645, Aug. 3, 1995]

## § 175.260 Partial phosphoric acid esters of polyester resins.

Partial phosphoric acid esters of polyester resins identified in this section and applied on aluminum may be safely used as food-contact coatings, in accordance with the following prescribed conditions:

(a) For the purpose of this section, partial phosphoric acid esters of polyester resins are prepared by the reaction of trimellitic anhydride with 2,2-dimethyl-1,3-propanediol followed by reaction of the resin thus produced with phosphoric acid anhydride to produce a resin having an acid number of 81 to 98 and a phosphorus content of 4.05 to 4.65 percent by weight.

(b) The coating is chemically bonded to the metal and cured at temperatures exceeding 450 °F.

(c) The finished food-contact coating, 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), yields total extractives in each extracting solvent not to exceed 0.3 milligrams per square inch of food-contact surface, as determined by the methods described in § 175.300(e), and the coating yields 2,2-dimethyl-1,3-propanediol in each extracting solvent not to exceed 0.3 micrograms per square inch of food-contact surface. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

## § 175.270 Poly(vinyl fluoride) resins.

Poly(vinyl fluoride) resins identified in this section may be safely used as components of food-contact coatings for containers having a capacity of not less than 5 gallons, subject to the provisions of this section.

(a) For the purpose of this section, poly(vinyl fluoride) resins consist of basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM method D1243–79, “Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428–2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) *Solvent.* *N,N*-Dimethylacetamide, technical grade.

(2) *Solution.* Powdered resin and solvent are heated at 120 °C until the resin is dissolved.

(3) *Temperature.* Flow times of the solvent and solution are determined at 110 °C.

(4) *Viscometer*. Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) *Calculation*. The calculation method used is that described in appendix X 1.3 (ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference; see paragraph (b) of this section for availability of the incorporation by reference) with the reduced viscosity determined for three concentration levels not greater than 0.5 gram per deciliter and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_0}{t_0 \times c}$$

where:

$t$  = Solution efflux time.

$t_0$  = Solvent efflux time.

$c$  = Concentration of solution in terms of grams per deciliter.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10107, Mar. 19, 1984]

#### § 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.  
Candlenut.  
Castor (including dehydrated).  
Chinawood (tung).  
Coconut.  
Corn.  
Cottonseed.  
Fish (refined).  
Hempseed.  
Linseed.  
Oiticica.  
Perilla.  
Poppyseed.  
Pumpkinseed.  
Safflower.  
Sesame.  
Soybean.  
Sunflower.  
Tall oil.  
Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.  
Ethylene glycol.  
Pentaerythritol.  
Polyethylene glycol.  
Polypropylene glycol.  
Propylene glycol.  
Sorbitol.  
Trimethylol ethane.  
Trimethylol propane.

§ 175.300

21 CFR Ch. I (4–1–16 Edition)

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.  
Butadiene and styrene copolymer, blown or unblown.  
Maleic anhydride adduct of butadiene styrene.  
Polybutadiene.

(iv) Natural fossil resins, as the basic resin:

Copal.  
Damar.  
Elemi.  
Gilsonite.  
Glycerol ester of damar, copal, elemi, and sandarac.  
Sandarac.  
Shellac.  
Utah coal resin.

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(a) Rosins, refined to color grade of K or paler:

Gum rosin.  
Tall oil rosin.  
Wood rosin.

(b) Rosin esters formed by reacting rosin (paragraph (b)(3)(v)(a) of this section) with:

4,4'-*sec*-Butylidenediphenol-epichlorohydrin (epoxy).  
Diethylene glycol.  
Ethylene glycol.  
Glycerol.  
4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).  
Methyl alcohol.  
Pentaerythritol.

(c) Rosin esters (paragraph (b)(3)(v)(b) of this section) modified by reaction with:

Maleic anhydride.  
*o*-, *m*-, and *p*-substituted phenol-formaldehydes listed in paragraph (b)(3)(vi) of this section.  
Phenol-formaldehyde.

(d) Rosin salts:

Calcium resinate (limed rosin).  
Zinc resinate.

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(a) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.  
*p*-*tert*-Amylphenol.  
4,4'-*sec*-Butylidenediphenol.  
*p*-*tert*-Butylphenol.  
*o*-, *m*-, and *p*-Cresol.  
*p*-Cyclohexylphenol.  
4,4'-Isopropylidenediphenol.  
*p*-Nonylphenol.  
*p*-Octylphenol.  
3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.  
Phenol.  
Phenyl *o*-cresol.  
*p*-Phenylphenol.  
Xylenol.

(b) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (a) and (b) of this section by reaction with alcohols in paragraph (b)(3)(vii) (c) and (d) of this section.

(a) Polybasic acids:

Adipic.  
1,4-cyclohexanedicarboxylic (CAS Reg. No. 1076-97-7).  
Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.  
Fumaric.  
Isophthalic.  
Maleic.  
2,6-Naphthalenedicarboxylic.  
2,6-Naphthalenedicarboxylic, dimethyl ester.  
Orthophthalic.  
Sebacic.  
Terephthalic.  
Terpene-maleic acid adduct.  
Trimellitic.

(b) Monobasic acids:

Benzoic acid.  
4,4-Bis(4'-hydroxyphenyl)-pentanoic acid.  
*tert*-Butyl benzoic acid.  
Fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.  
Rosins listed in paragraph (b)(3)(v)(a) of this section, for use only as reactants in oil-based or fatty acid-based alkyd resins.

(c) Polyhydric alcohols:

Butylene glycol.  
Diethylene glycol.  
2,2-Dimethyl-1,3-propanediol for use only in forming polyester resins for coatings intended for use in contact with non-alcoholic foods.  
Ethylene glycol.  
Glycerol.  
Mannitol.  
 $\alpha$ -Methyl glucoside.  
Pentaerythritol.

**Food and Drug Administration, HHS**

**§ 175.300**

Propylene glycol.

Sorbitol.

Triethylene glycol, for use as a component in polyester resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Trimethylol ethane.

Trimethylol propane.

**(d) Monohydric alcohols:**

Cetyl alcohol.

Decyl alcohol.

Lauryl alcohol.

Myristyl alcohol.

Octyl alcohol.

Stearyl alcohol.

**(e) Catalysts:**

Dibutyltin oxide (CAS Reg. No. 818-08-6), not to exceed 0.2 percent of the polyester resin.

Hydroxybutyltin oxide (CAS Reg. No. 2273-43-0), not to exceed 0.2 percent of the polyester resin.

Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850-94-4), not to exceed 0.2 percent of the polyester resin.

**(viii) Epoxy resins, catalysts, and adjuncts:**

**(a) Epoxy resins, as the basic polymer:**

(Alkoxy C<sub>10</sub>-C<sub>16</sub>)-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C<sub>10</sub> carbon atoms and a minimum of 48 percent C<sub>12</sub> carbon atoms and a minimum of 18 percent C<sub>14</sub> carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.

4,4'-*sec*-Butylidenediphenol-epichlorohydrin.

4,4'-*sec*-Butylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4'-*sec*-Butylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4'-*sec*-Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

Phenol-formaldehyde.

Urea-formaldehyde.

Epoxidized polybutadiene.

Glycidyl ethers formed by reacting phenolnovolak resins with epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils

or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4'-Isopropylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4'-*sec*-Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]]bisoxirane, CAS Reg. No. 71033-08-4, for use only in coatings intended for contact with bulk dry foods at temperatures below 100 °F.

Phenol-formaldehyde.

Urea-formaldehyde.

**(b) Catalysts and cross-linking agents for epoxy resins:**

3-(Aminomethyl)-3,5,5-trimethylcyclohexylamine reacted with phenol and formaldehyde in a ratio of 2.6:1.0:2.0, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Category I and Category VIII, at temperatures not exceeding 88 °C (190 °F).

N-*Beta*-(aminoethyl)-*gamma*-aminopropyltrimethoxysilane (CAS Reg. No. 1760-24-3), for use only in coatings at a level not to exceed 1.3 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Benzyl alcohol (CAS Reg. No. 100-51-6), for use only in coatings at a level not to exceed 4 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

**§ 175.300**

Catalysts and cross-linking agents for epoxy resins:

3-Aminomethyl-3,5,5-trimethylcyclohexylamine (CAS Reg. No. 2855-0913-092).

Cyanoguanidine.

Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

3-Diethylaminopropylamine (CAS Reg. No. 104-78-9), for use in coatings at a level not to exceed 6 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Diethylenetriamine.

Diphenylamine.

Ethylenediamine.

Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

4,4'-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

N-Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.

3-Pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 (CAS Reg. No. 68413-28-5).

Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of N-octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c) (3) or (4) of this section and that contact food at temperatures not to exceed room temperature.

Polyethylenepolyamine (CAS Reg. No. 68131-73-7), for use only in coatings intended for repeated use in contact with food, at temperatures not to exceed 180 °F (82 °C).

Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with al-

coholic beverages containing up to 8 percent of alcohol by volume.

Salicylic acid (CAS Reg. No. 69-72-7), for use only in coatings at a level not to exceed 0.35 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Tetraethylenepentamine.

Tetraethylenepentamine reacted with equimolar quantities of fatty acids.

Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(b) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

Triethylenetetramine.

Trimellitic anhydride (CAS Reg. No. 552-30-7) for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin in contact with food under all conditions of use, except that resins intended for use with foods containing more than 8 percent alcohol must contact such food only under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Trimellitic anhydride adducts of ethylene glycol and glycerol, prepared by the reaction of 1 mole of trimellitic anhydride with 0.4-0.6 mole of ethylene glycol and 0.04-0.12 mole of glycerol, for use only as a cross-linking agent at a level not to exceed 10 percent by weight of the cured coating, provided that the cured coating only contacts food containing not more than 8 percent alcohol.

Meta-Xylylenediamine (1,3-benzenedimethanamine, CAS Reg. No. 1477-55-0), for use only in coatings at a level not to exceed 3 percent by weight of the resin when such coatings are intended for repeated use

**21 CFR Ch. I (4-1-16 Edition)**

in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Para-Xylylenediamine (1,4 benzenedimethanamine, CAS Reg. No. 539-48-0), for use only in coatings at a level not to exceed 0.6 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E and F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

(c) Adjuncts for epoxy resins:

Aluminum butylate.

Benzoic acid, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(b) of this section, as the basic polymer.

Silane coupled silica, prepared from the reaction of microcrystalline quartz with *N*-beta-(*N*-vinylbenzylamino) ethyl-gamma-aminopropyltrimethoxy silane, monohydrogen chloride, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Category I and Category VIII, at temperatures not exceeding 88 °C (190 °F).

Succinic anhydride, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch, and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

(ix) Coumarone-indene resin, as the basic polymer.

(x) Petroleum hydrocarbon resin (cyclopentadiene type), as the basic polymer.

(xi) Terpene resins, as the basic polymer, from one or more of the following:

Dipentene.

Hydrogenated dipentene resin (CAS Reg. No. 106168-39-2). For use only with coatings in contact with acidic and aqueous foods.

Hydrogenated-beta-pinene-alpha-pinene-dipentene copolymer resin (CAS Reg. No. 106168-37-0). For use only with coatings in contact with acidic and aqueous foods.

α-Pinene.

β-Pinene.

(xii) Urea-formaldehyde, resins and their curing catalyst:

(a) Urea-formaldehyde resins, as the basic polymer:

Urea-formaldehyde.

Urea-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in paragraph (b)(3)(viii)(b) of this section.

(b) Curing (cross-linking) catalyst for urea-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiii) Triazine-formaldehyde resins and their curing catalyst:

(a) Triazine-formaldehyde resins, as the basic polymer:

Benzoguanamine-formaldehyde.

Melamine-formaldehyde.

Melamine-formaldehyde chemically modified with one or more of the following amine catalysts:

Amine catalysts listed in paragraph (b)(3)(viii)(b) of this section.

Dimethylamine-2-methyl-1-propanol.

Methylpropanolamine.

Triethanolamine.

Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

(b) Curing (cross-linking) catalyst for triazine-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiv) Modifiers (for oils and alkyds, including polyesters), as the basic polymer:

Butyl methacrylate.

Cyclopentadiene.



**§ 175.300**

Methyl, ethyl, butyl, or octyl esters of acrylic acid.  
Methyl methacrylate.  
Styrene.  
Vinyl toluene.

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.  
Polyvinyl alcohol.  
Polyvinyl butyral.  
Polyvinyl chloride.  
Polyvinyl formal.  
Polyvinylidene chloride.  
Polyvinyl pyrrolidone.  
Polyvinyl stearate.

Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.

Vinyl chloride-acetate, hydroxyl-modified copolymer.

Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.

Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed.

Vinyl chloride copolymerized with one or more of the following substances:

Acrylonitrile.

Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.

Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.

5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.

Vinyl acetate.

Vinylidene chloride.

Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions B, C, D, E, F, G, or H described in table 2 of paragraph (d) of this section.

**21 CFR Ch. I (4-1-16 Edition)**

(xvi) Cellulosics, as the basic polymer:

Carboxymethylcellulose.  
Cellulose acetate.  
Cellulose acetate-butyrate.  
Cellulose acetate-propionate.  
Ethylcellulose.  
Ethyl hydroxyethylcellulose.  
Hydroxyethylcellulose.  
Hydroxypropyl methylcellulose.  
Methylcellulose.  
Nitrocellulose.

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.  
 $\alpha$ -Methyl styrene polymer.  
Styrene copolymerized with one or more of the following:  
Acrylonitrile.  
 $\alpha$ -Methylstyrene.

(xviii) Polyethylene and its copolymers as the basic polymer:

Ethylene-ethyl acrylate copolymer.  
Ethylene-isobutyl acrylate copolymers containing no more than 35 weight percent of total polymer units derived from isobutyl acrylate.  
Ethylene-vinyl acetate copolymer.  
Polyethylene.

(xix) Polypropylene as the basic polymer:

Polypropylene.

Maleic anhydride adduct of polypropylene  
The polypropylene used in the manufacture of the adduct complies with §177.1520(c), item 1.1; and the adduct has a maximum combined maleic anhydride content of 0.8 percent and a minimum intrinsic viscosity of 0.9, determined at 135 °C on a 0.1 percent solution of the modified polypropylene in decahydronaphthalene as determined by a method titled "Method for Determination of Intrinsic Viscosity of Maleic Anhydride Adduct of Polypropylene," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(xx) Acrylics and their copolymers, as the basic polymer:

Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.

Acrylic acid and the following esters thereof:  
Ethyl.  
Methyl.

Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.

Butyl acrylate-styrene-methacrylic acid-hydroxypropyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxypropyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates and that are intended for contact, under condition of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

Ethyl acrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(a) of this section.

Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(a) of this section.

2-Ethylhexyl acrylate-ethyl acrylate copolymers prepared by copolymerization of 2-ethylhexyl acrylate and ethyl acrylate in a 7/3 weight ratio and having a number average molecular weight range of 5,800 to 6,500 and a refractive index,  $n_{D25}^{\circ}$  (40 percent in 2,2,4-trimethyl pentane) of 1.4130-1.4190; for use as a modifier for nylon resins complying with §177.1500 of this chapter and for phenolic and epoxy resins listed in paragraph (b)(3)(vi) and (viii) of this section, respectively, at a level not to exceed 1.5 percent of the coating.

2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii) of this section.

Methacrylic acid and the following esters thereof:

Butyl.  
Ethyl.  
Methyl.

Methacrylic acid or its ethyl and methyl esters copolymerized with one or more of the following:

Acrylic acid.  
Ethyl acrylate.  
Methyl acrylate.

*n*-Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers

containing no more than 2 weight percent of total polymer units derived from methacrylic acid and containing no more than 9.5 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings in contact with dry food (food type VIII in table 1 of paragraph (d) of this section). 2-(Dimethylamino) ethanol (C.A.S. Registry No. 108-01-0) may be employed as an optional adjuvant substance limited to no more than 2 weight percent based on polymer solids in the coating emulsion.

Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight ( $M_n$ ) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent. The polymers are for use only in contact with food of Types IV-A, V, VII in table 1 of paragraph (d) of this section, under use conditions E through G in table 2 of paragraph (d), and with food of Type VIII without use temperature restriction.

(xxi) Elastomers, as the basic polymer:

Butadiene-acrylonitrile copolymer.  
Butadiene-acrylonitrile-styrene copolymer.  
Butadiene-styrene copolymer.  
Butyl rubber.  
Chlorinated rubber.  
2-Chloro-1,3-butadiene (neoprene).  
Natural rubber (natural latex or natural latex solids, smoked or unsmoked).  
Polyisobutylene.  
Rubber hydrochloride.  
Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a metal from paragraph (b)(3)(xxii)(a) of this section with acid, to form the salt listed in paragraph (b)(3)(xxii)(b) of this section:

(a) Metals:

Aluminum.  
Calcium.  
Cerium.  
Cobalt.  
Iron.  
Lithium.  
Magnesium.  
Manganese.  
Zinc.  
Zirconium.

**§ 175.300**

**21 CFR Ch. I (4–1–16 Edition)**

**(b) Salts:**

Caprate.  
Caprylate.  
Isodecanoate.  
Linoleate.  
Naphthenate.  
Neodecanoate.  
Octoate (2-ethylhexoate).  
Oleate.  
Palmitate.  
Resinate.  
Ricinoleate.  
Soyate.  
Stearate.  
Tallate.

**(xxiii) Waxes:**

Paraffin, Type I.  
Paraffin, Type II.  
Polyethylene.  
Sperm oil.  
Spermaceti.

**(xxiv) Plasticizers:**

Acetyl tributyl citrate.  
Acetyl triethyl citrate.  
Butyl phthalyl butyl glycolate.  
Butyl stearate.  
*p-tert*-Butyl phenyl salicylate.  
Dibutyl sebacate.  
Diethyl phthalate.  
Diisobutyl adipate.  
Diisooctyl phthalate.  
Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.  
Ethyl phthalyl ethyl glycolate.  
2-Ethylhexyl diphenyl phosphate.  
di-2-Ethylhexyl phthalate.  
Glycerol.  
Glyceryl monooleate.  
Glyceryl triacetate.  
Monoisopropyl citrate.  
Propylene glycol.  
Sorbitol.  
Mono-, di-, and tristearyl citrate.  
Triethyl citrate.  
Triethylene glycol.  
3-(2-Xenolyl)-1,2-epoxypropane.

**(xxv) Release agents, as the basic polymer, when applicable:**

*N,N'*-Dioleoylthylenediamine (CAS Reg. No. 110-31-6) for use only in ionomeric resins complying with §177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with §177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.  
*N,N'*-Distearoyl thylenediamine.  
Linoleic acid amide.  
Oleic acid amide.  
Palmitic acid amide.

Petrolatum.  
Polyethylene wax.  
Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).  
Polytetrafluoroethylene.  
Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.  
Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

**(xxvi) Colorants used in accordance with §178.3297 of this chapter.**

**(xxvii) Surface lubricants:**

Cottonseed oil and other edible oils.  
Dibutyl sebacate.  
Diocetyl sebacate.  
Glyceryl monostearate.  
Lanolin.  
Mineral oil, white.  
Palm oil.  
Paraffin, Type I.  
Paraffin, Type II.  
Petrolatum.  
Stearic acid.

**(xxviii) Silicones and their curing catalysts:**

**(a) Silicones as the basic polymer:**

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.  
Siloxane resins originating from the platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083-18-1 and CAS Reg. No. 68083-19-2) with methylhydrogen polysiloxane (CAS Reg. No. 63148-57-2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037-59-2), where the platinum content does not exceed 150 parts per million. The following substances may be used as optional polymerization inhibitors:  
3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107-54-0), at a level not to exceed 0.53 weight-percent;  
1-Ethynylcyclohexene (CAS Reg. No. 931-49-7), at a level not to exceed 0.64 weight-percent;  
Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054-10-4), at a level not to exceed 1.0 weight-percent;  
Methylvinyl cyclosiloxane (CAS Reg. No. 68082-23-5); and

## Food and Drug Administration, HHS

§ 175.300

Tetramethyltetravinylcyclotetrasiloxane  
(CAS Reg. No. 2554-06-5).

(b) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.  
Stannous oleate.  
Tetrabutyl titanate.

(xxix) Surface active agents:

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).  
Poly[2-(diethylamino) ethyl methacrylate] phosphate (minimum intrinsic viscosity in water at 25 °C is not less than 9.0 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.

Sodium dioctyl sulfosuccinate.

Sodium dodecylbenzenesulfonate

Sodium lauryl sulfate.

2,4,7,9-Tetramethyl-5-decyn-4,7-diol (C.A.S. Reg. No. 126-86-3), for use only in can coatings which are subsequently dried and cured at temperatures of at least 193 °C (380 °F) for 4 minutes.

(xxx) Antioxidants:

Butylated hydroxyanisole.  
Butylated hydroxytoluene.  
Gum guaiac.  
Dilauryl thiodipropionate.  
Nordihydroguaiaretic acid.  
Propyl gallate.  
Distearyl thiodipropionate.  
Thiodipropionic acid.  
2,4,5-Trihydroxybutyrophenone.

(xxxii) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in §177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-divinylbenzene copolymer (CAS Reg. No. 26471-45-4) for use only at levels not to exceed 23.8 percent by weight of the cement solids in can end cements.

Butadiene-styrene-fumaric acid copolymer.

4,4'-Butylidenebis (6-*tert*-butyl-*m*-cresol).

Dibenzamido phenyl disulfide.

Di-β-naphthyl phenylenediamine.

Dipentamethylene thiuram tetrasulfide.

Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.

Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium decylbenzene sulfonate.

Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Sodium phenylphenate.

Styrene-maleic anhydride resin, partial methyl and butyl (*sec*- or *iso*-) esters, for use only at levels not in excess of 3 percent of the cement solids in can end cement formulations.

Tetrasodium EDTA (tetrasodium ethylenediaminetetraacetate).

Tri (mixed mono- and dinonylphenyl) phosphite.

Zinc dibutyldithiocarbamate.

(xxxii) Side seam cements: In addition to the substances listed in paragraph (b)(3) (i) to (xxx), inclusive, of this section, the following may be used.

*p*-*tert*-Butyl perbenzoate as a catalyst for epoxy resin.

*epsilon*-Caprolactam-(ethylene-ethyl acrylate) graft polymer.

Dicumyl peroxide for use only as polymerization catalyst.

4-(Diiodomethylsulfonyl) toluene (CAS Reg. No. 20018-09-1) for use as a preservative at a level not to exceed 0.3 percent by weight in can-sealing cements.

Diisodecyl phthalate for use only as plasticizer in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under Categories I, II, and VI.

4,4'-Bis(*alpha*,*alpha*-dimethylbenzyl)diphenylamine, CAS Reg. No. 10081-67-1.

Ethyl toluene sulfonamide.

## § 175.300

*N,N'*-Hexamethylenebis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamide), CAS Reg. No. 23128-74-7.

Polyamides consisting of the following:

Copolymer of *omega*-laurolactam and *epsilon*-caprolactam, CAS Reg. No. 25191-04-2 (Nylon 12/6).

Homopolymer of *omega*-aminododecanoic acid, CAS Reg. No. 24937-16-4.

Homopolymer of *omega*-laurolactam, CAS Reg. No. 25038-74-8 (Nylon 12).

Polyamides derived from the following acids and amines:

Acids:

Adipic.

Azelaic.

Sebacic.

Vegetable oil acids (with or without dimerization).

Amines:

Diethylenetriamine.

Diphenylamine.

Ethylenediamine.

Hexamethylenediamine.

Tetraethylenepentamine.

Triethylenetetramine.

Polypropylene glycol CAS Reg. No. 25322-69-4.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Tetrakis [methylene(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)]methane, CAS Reg. No. 6683-19-8.

Toluene sulfonamide formaldehyde resin (basic polymer).

Triethylene glycol methacrylate for use only as polymerization cross-linking agent in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under Categories I, II, and VI.

Urea.

(xxxiii) Miscellaneous materials:

Ammonium citrate.

Ammonium potassium phosphate.

Bentonite, modified by reaction with benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 71011-24-0). For use only as a rheological agent in coatings intended to contact food under repeated use conditions.

Bentonite, modified by reaction with sodium stearate and benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-68-4). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

Calcium acetate.

Calcium ethyl acetoacetate.

Calcium glycerophosphate.

## 21 CFR Ch. I (4-1-16 Edition)

Calcium, sodium, and potassium oleates.

Calcium, sodium, and potassium ricinoleates.

Calcium, sodium, and potassium stearates.

Castor oil, hydrogenated.

Castor oil, hydrogenated polymer with ethylenediamine, 12-hydroxyoctadecanoic acid and sebacic acid (CAS Reg. No. 68604-06-8). The condensation product formed by the reaction of hydrogenated castor oil with polyamide derived from ethylenediamine, sebacic acid and 12-hydroxystearic acid, for use only in coatings at a level not to exceed 3.2 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Castor oil, sulfated, sodium salt (CAS Reg. No. 68187-76-8), for use only in coatings for containers intended for repeated use.

Cetyl alcohol.

5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight). For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulations.

Cyclohexanone-formaldehyde resin produced when 1 mole of cyclohexanone is made to react with 1.65 moles of formaldehyde such that the finished resin has an average molecular weight of 600-610 as determined by ASTM method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)

## Food and Drug Administration, HHS

§ 175.300

*code\_of\_federal\_regulations/*

*ibr\_locations.html*. For use only in contact with nonalcoholic and nonfatty foods under conditions of use E, F, and G, described in table 2 of paragraph (d) this section.

Decyl alcohol.

1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7). For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coatings.

Disodium hydrogen phosphate.

Ethyl acetoacetate.

Hectorite, modified by reaction with a mixture of benzyl methyl dialkyl ammonium chloride and dimethyl dialkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-67-3). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

Lauryl alcohol.

Lecithin.

Magnesium, sodium, and potassium citrate.

Magnesium glycerophosphate.

Magnesium stearate.

Mono-, di-, and tricalcium phosphate.

Monodibutylamine pyrophosphate as sequestrant for iron.

Mono-, di-, and trimagnesium phosphate.

Myristyl alcohol.

Octyl alcohol.

Phosphoric acid.

Polybutene, hydrogenated; complying with the identity and limitations prescribed by §178.3740 of this chapter.

Poly(ethylene oxide).

Siloxanes and silicones, dimethyl, 3-hydroxypropyl group-terminated, diesters with poly(2-oxepanone), diacetates (CAS Reg. No. 116810-47-0) at a level not to exceed 0.025 weight percent of the finished coating having no greater than a 0.5 mil thickness for use as a component of polyester, epoxy, and acrylic coatings complying with paragraphs (b)(3)(vii), (viii), and (xx) of this section, respectively.

Silver chloride-coated titanium dioxide for use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.

Sodium pyrophosphate.

Stannous chloride.

Stannous stearate.

Stannous sulfate.

Stearyl alcohol.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on metal under conditions of use E, F, and G described in table 2 of paragraph (d) of this section, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

Tetrasodium pyrophosphate.

Tridecyl alcohol produced from tetrapropylene by the oxo process, for use only as a processing aid in polyvinyl chloride resins.

Trimethylolpropane (CAS Reg. No. 77-99-6).

For use as a pigment dispersant at levels not to exceed 0.45 percent by weight of the pigment.

Vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers: Acrylic acid or glycidyl methacrylate. For use only in coatings for metal foil used in contact with foods that are dry solids with the surface containing no free fat or oil. The finished copolymers shall contain at least 50 weight-percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight-percent of total polymer units derived from acrylic acid or glycidyl methacrylate.

(xxxiv) Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine, as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature.

(xxxv) Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

(xxxvi) Methacrylonitrile grafted polybutadiene copolymers containing no more than 41 weight percent of total polymer units derived from methacrylonitrile; for use only in coatings that are intended for contact, under conditions of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

(xxxvii) Polymeric resin as a coating component prepared from terephthalic acid, isophthalic acid, succinic anhydride, ethylene glycol, diethylene glycol, and 2,2-dimethyl-1,3-propanediol

§ 175.300

21 CFR Ch. I (4–1–16 Edition)

for use in contact with aqueous foods and alcoholic foods containing not more than 20 percent (by volume) of alcohol under conditions of use D, E, F, and G described in table 2 of §176.170 of this chapter. The resin shall contain no more than 30 weight percent of 2,2-dimethyl-1,3-propanediol.

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of paragraph (d) of this section, shall yield chloroform-soluble extractives, corrected for zinc extractives as zinc oleate, not to exceed the following:

(1) From a coating intended for or employed as a component of a container not to exceed 1 gallon and intended for one-time use, not to exceed 0.5 milligram per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container, in milligrams, divided by the area of the food-contact surface of the container in square inches. From a fabricated container conforming with the description in this paragraph (c)(1), the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container as determined by the methods provided in paragraph (e) of this section.

(2) From a coating intended for or employed as a component of a container having a capacity in excess of 1 gallon and intended for one-time use, not to exceed 1.8 milligrams per square

inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(3) From a coating intended for or employed as a component of a container for repeated use, not to exceed 18 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(4) From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface.

(d) Tables:

TABLE 1—TYPES OF FOOD

- I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsion, high- or low-fat.
  - B. Oil-in-water emulsion, high- or low-fat.
- V. Low moisture fats and oils.
- VI. Beverages:
  - A. Containing alcohol.
  - B. Nonalcoholic.
- VII. Bakery products.
- VIII. Dry solids (no end test required).

TABLE 2—TEST PROCEDURES FOR DETERMINING AMOUNT OF EXTRACTIVES FROM RESINOUS OR POLYMERIC COATINGS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see Table 1)	Extractant		
		Water (time and temperature)	Heptane <sup>1 2</sup> (time and temperature)	8% alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV–B .....	250 °F, 2 hr .....	.	
	III, IV–A, VII .....	do .....	150 °F, 2 hr.	
B. Boiling water-sterilized	II .....	212 °F, 30 min .....	.	
	III, VII .....	do .....	120 °F, 30 min.	
C. Hot filled or pasteur- ized above 150 °F.	II, IV–B .....	Fill boiling, cool to 100 °F.	.	
	III, IV–A .....	do .....	120 °F, 15 min.	
	V .....	do .....	do.	

TABLE 2—TEST PROCEDURES FOR DETERMINING AMOUNT OF EXTRACTIVES FROM RESINOUS OR POLYMERIC COATINGS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES—Continued

Condition of use	Types of food (see Table 1)	Extractant		
		Water (time and temperature)	Heptane <sup>1 2</sup> (time and temperature)	8% alcohol (time and temperature)
D. Hot filled or pasteurized below 150 °F.	II, IV-B, VI-B .....	150 °F, 2 hr .....	.	150 °F, 2 hr.
	III, IV-A .....	do .....	100 °F, 30 min.	
	V .....	.....	do.	
	VI-A .....	.....	.....	
E. Room temperature filled and stored (no thermal treatment in the container).	II, IV-B, VI-B .....	120 °F, 24 hr .....	.	120 °F, 24 hr.
	III, IV-A .....	do .....	70 °F, 30 min.	
	V, VII .....	.....	do.	
	VI-A .....	.....	.....	
F. Refrigerated storage (no thermal treatment in the container).	I, II, III, IV-A, IV-B, VI-B, VII.	70 °F, 48 hr .....	.	70 °F, 48 hr.
	VI-A .....	.....	.....	
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII ...	70 °F, 24 hr .....	.	
H. Frozen storage: Ready-prepared foods intended to be reheated in container at time of use:				
	1. Aqueous or oil in water emulsion of high or low fat.	I, II, IV-B .....	212 °F, 30 min .....	.
	2. Aqueous, high or low free oil or fat.	III, IV-A, VII .....	do .....	120 °F, 30 min.

<sup>1</sup> Heptane extractant not to be used on wax-lined containers.<sup>2</sup> Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

(e) *Analytical methods*—(1) *Selection of extractability conditions*. First ascertain the type of food product (table 1, paragraph (d) of this section) that is being packed commercially in the test container and the normal conditions of thermal treatment used in packaging the type of food involved. Using table 2 (paragraph (d) of this section), select the food-simulating solvent or solvents (demineralized distilled water, heptane, and/or 8 percent ethyl alcohol) and the time-temperature exaggerations of the container-use conditions. Aqueous products (Types I, II, IV-B, and VI-B) require only a water-extractability test at the temperature and time conditions shown for the most severe “conditions of use.” Aqueous products with free oil or fat, and water-oil emulsions (types III, IV-A, and VII) will require determinations of both water extractability and heptane extractability. Low-moisture fats and oils (type V with no free water) require

only the heptane extractability. Alcoholic beverages (type VI-A) require only the 8 percent alcohol extractant. Having selected the appropriate extractant or extractants simulating various types of foods and beverages and the time-temperature exaggerations over normal use, follow the applicable extraction procedure. Adapt the procedure, when necessary, for containers having a capacity of over 1 gallon.

(2) *Selection of coated-container samples*. For consumer-sized containers up to 1 gallon, quadruplicate samples of representative containers (using for each replicate sample the number of containers nearest to an area of 180 square inches) should be selected from the lot to be examined.

(3) *Cleaning procedure preliminary to determining the amount of extractables from coated containers*. Quadruplicate samples of representative containers should be selected from the lot to be examined and must be carefully rinsed



to remove extraneous material prior to the actual extraction procedure. Soda fountain pressure-type hot water rinsing equipment, consisting in its simplest form of a 1/8-inch-1/4-inch internal diameter metal tube attached to a hot water line and bent so as to direct a stream of water upward, may be used. Be sure hot water has reached a temperature of 190 °F–200 °F before starting to rinse the container. Invert the container over the top of the fountain and direct a strong stream of hot water against the bottom and all sides for 1 minute, drain, and allow to dry.

(4) *Exposure conditions*—(i) *Water (250 °F for 2 hours), simulating high-temperature heat sterilization.* Fill the container within 1/4-inch of the top with a measured volume of demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker. Add a small amount of demineralized distilled water to the pressure cooker, but do not allow the water to touch the bottom of the container. Close the cooker securely and start to heat over a suitable burner. When a steady stream of steam emerges from the vent, close the vent and allow the pressure to rise to 15 pounds per square inch (250 °F) and continue to maintain this pressure for 2 hours. Slowly release the pressure, open the pressure cooker when the pressure reads zero, and composite the water of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ii) *Water (212 °F for 30 minutes), simulating boiling water sterilization.* Fill the container within 1/4-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or

beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iii) *Water (from boiling to 100 °F), simulating hot fill or pasteurization above 150 °F.* Fill the container within 1/4-inch of the top with a measured volume of boiling, demineralized distilled water. Insert a thermometer in the water and allow the uncovered container to stand in a room at 70 °F–85 °F. When the temperature reads 100 °F, composite the water from each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iv) *Water (150° for 2 hours), simulating hot fill or pasteurization below 150 °F.* Preheat demineralized distilled water to 150 °F in a clean Pyrex flask. Fill the container within 1/4-inch of the top with a measured volume of the 150 °F water and cover with clean aluminum foil. Place the test container in an oven maintained at 150 °F. After 2 hours, remove the test container from the oven and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(v) *Water (120 °F for 24 hours), simulating room temperature filling and storage.* Preheat demineralized distilled water to 120 °F in a clean Pyrex flask. Fill the container within 1/4-inch of the top with a measured volume of the 120 °F water and cover with clean aluminum foil. Place the test container in an incubator or oven maintained at 120 °F. After 24 hours, remove the test container from the incubator and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vi) *Water (70 °F for 48 hours), simulating refrigerated storage.* Bring demineralized distilled water to 70 °F in a clean Pyrex flask. Fill the container within 1/4-inch of the top with a measured volume of the 70 °F water, and cover with clean aluminum foil.

Place the test container in a suitable room maintained at 70 °F. After 48 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vii) *Water (70 °F for 24 hours), simulating frozen storage.* Bring demineralized distilled water to 70 °F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70 °F water and cover with clean aluminum foil. Place the container in a suitable room maintained at 70 °F. After 24 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(viii) *Water (212 °F for 30 minutes), simulating frozen foods reheated in the container.* Fill the container to within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ix) *Heptane (150 °F for 2 hours) simulating high-temperature heat sterilization for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 °F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150 °F. At the same time preheat a pressure cooker or equivalent to 150 °F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a

measured volume of the 150 °F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150 °F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(x) *Heptane (120 °F for 30 minutes), simulating boiling water sterilization of fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 °F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120 °F. At the same time, preheat a pressure cooker or equivalent to 120 °F in an incubator. This pressure cooker is to serve only as a vented container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120 °F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120 °F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xi) *Heptane (120 °F for 15 minutes), simulating hot fill or pasteurization above 150 °F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 °F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120 °F. At the same time, preheat a pressure cooker or equivalent to 120 °F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120 °F heptane and cover with clean aluminum foil. Place the test container in the

preheated pressure cooker and then put the assembly into a 120 °F incubator. After 15 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xii) *Heptane (100 °F for 30 minutes), simulating hot fill or pasteurization below 150 °F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 °F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 100 °F. At the same time, preheat a pressure cooker or equivalent to 100 °F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 100 °F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 100 °F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiii) *Heptane (70 °F for 30 minutes), simulating room temperature filling and storage of fatty foods only.* Fill the test container within ¼-inch of the top with a measured volume of the 70 °F heptane and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70 °F. After 30 minutes, composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiv) *Heptane (120 °F for 30 minutes), simulating frozen fatty foods reheated in the container.* Preheat redistilled reagent-grade heptane (boiling point 208 °F) carefully in a clean Pyrex flask on a water bath or hot plate in a well-ventilated hood to 120 °F. At the same

time, preheat a pressure cooker to 120 °F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120 °F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120 °F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xv) *Alcohol—8 percent (150 °F for 2 hours), simulating alcoholic beverages hot filled or pasteurized below 150 °F.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 150 °F in a clean Pyrex flask. Fill the test container with within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil and place in an oven maintained at 150 °F. After 2 hours, remove the container from the oven and immediately composite the alcohol from each replicate in a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvi) *Alcohol—8 percent (120 °F for 24 hours), simulating alcoholic beverages room-temperature filled and stored.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 120 °F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol, cover the container with clean aluminum foil and place in an oven or incubator maintained at 120 °F. After 24 hours, remove the container from the oven or incubator and immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvii) *Alcohol—8 percent (70 °F for 48 hours), simulating alcoholic beverages in*

*refrigerated storage.* Bring 8 percent (by volume) ethyl alcohol in demineralized distilled water to 70 °F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil. Place the test container in a suitable room maintained at 70 °F. After 48 hours, immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

NOTE: The tests specified in paragraph (e)(4) (i) through (xvii) of this section are applicable to flexible packages consisting of coated metal contacting food, in which case the closure end is double-folded and clamped with metal spring clips by which the package can be suspended.

(5) *Determination of amount of extractives*—(i) *Total residues.* Evaporate the food-simulating solvents from paragraph (e)(4) (i) to (xvii), inclusive, of this section to about 100 milliliters in the Pyrex flask and transfer to a clean, tared platinum dish, washing the flask three times with the solvent used in the extraction procedure, and evaporate to a few milliliters on a non-sparking low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 212 °F. Cool the platinum dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram (*e*). Calculate the extractives in milligrams per square inch and in parts per million for the particular size of container being tested and for the specific food-simulating solvent used.

(a) *Water and 8-percent alcohol.*

$$\text{Milligrams extractives per square inch} = \frac{e}{s}$$

$$\text{Extractives residue} = \frac{Ex = (e)(a)(1000)}{(c)(s)}$$

(b) *Heptane.*

$$\text{Milligrams extractives per square inch} = \frac{e}{(s)(F)}$$

$$\text{Extractives residue} = \frac{Ex = (e)(a)(1000)}{(c)(s)(F)}$$

where:

*Ex* = Extractives residue in ppm for any container size.

*e* = Milligrams extractives per sample tested.

*a* = Total coated area, including closure in square inches.

*c* = Water capacity of container, in grams.

*s* = Surface of coated area tested, in square inches.

*F* = Five, the ratio of the amount of extractives removed from a coated container by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil from a container tested under exaggerated conditions of thermal sterilization and use.

*e'* = Chloroform-soluble extractives residue.

*ee'* = Zinc corrected chloroform-soluble extractive residue.

*e'* or *ee'* is substituted for *e* in the above equations when necessary.

If when calculated by the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section, the concentration of extractives residue (*Ex*) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to paragraph (e)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the platinum dish, obtained in paragraph (e)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper in a Pyrex funnel, collecting the filtrate in a clean, tared platinum dish. Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 212 °F. Cool the platinum dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e'*). This *e'* is substituted for *e* in the equations in

## § 175.320

paragraph (e)(5)(i) (a) and (b) of this section. If the concentration of extractives (*Ex*) still exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed as follows to correct for zinc extractives ("C" enamels only): Ash the residue in the platinum dish by heating gently over a Meeker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the platinum dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e'*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* is substituted for *e* in the formulas in paragraph (e)(5)(i) (a) and (b) of this section. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for the zinc extractives in case of "C" enamels) must not exceed 50 parts per million and must not exceed in milligrams per square inch the limitations for the particular article as prescribed in paragraph (c) of this section.

(f) *Equipment and reagent requirements*—(1) *Equipment*.

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a 1/8-inch-1/4-inch inside diameter metal tube attached to a hot water line delivering 190 °F-200 °F water and bent so as to direct a stream of water upward.

Pressure cooker, 21-quart capacity with pressure gage, safety release, and removable rack, 12.5 inches inside diameter × 11 inches inside height, 20 pounds per square inch safe operating pressure.

Oven, mechanical convection, range to include 120 °F-212 °F explosion-proof, inside dimensions (minimum), 19" × 19" × 19", constant temperature to ±2 °F (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" × 19" × 19" for use at 100 °F±2 °F explosion proof (water bath may be substituted).

Constant-temperature room or chamber 70 °F±2 °F minimum inside dimensions 19" × 19" × 19".

## 21 CFR Ch. I (4-1-16 Edition)

Hot plate, nonsparking (explosion proof), top 12" × 20", 2,500 watts, with temperature control.

Platinum dish, 100-milliliter capacity minimum.

All glass, Pyrex or equivalent.

### (2) *Reagents*.

Water, all water used in extraction procedure should be freshly demineralized (deionized) distilled water.

Heptane, reagent grade, freshly redistilled before use, using only material boiling at 208 °F.

Alcohol, 8 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized or distilled water.

Chloroform, reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

Filter paper, Whatman No. 41 or equivalent.

(g) In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food.

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

(i) Epoxy resins derived by the reaction of 4,4'-isopropylidenediphenol and epichlorohydrin, as described in paragraph (b)(3)(viii)(a) of this section, may be used in accordance with this section except as coatings in packaging for powdered and liquid infant formula.

[42 FR 14534, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §175.300, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

## § 175.320 Resinous and polymeric coatings for polyolefin films.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from one or more of the basic olefin polymers complying with §177.1520 of this chapter. The base

**Food and Drug Administration, HHS**

**§ 175.320**

polyolefin film may contain optional adjuvant substances permitted for use in polyolefin film by applicable regulations in parts 170 through 189 of this chapter.

(b) The coatings are formulated from optional substances which are:

(1) Substances generally recognized as safe for use in or on food.

(2) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, by prior sanctions, or approvals.

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

List of substances	Limitations
<p>(i) Resins and polymers:</p> <p>Acrylic acid polymer and its ethyl or methyl esters.</p> <p>Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol.</p> <p>Butadiene-acrylonitrile copolymer.</p> <p>Butadiene-acrylonitrile-styrene terpolymer.</p> <p>Butyl rubber.</p> <p><i>N,N</i>-Diphenyl-<i>p</i>-phenylenediamine .....</p> <p>2-Ethylhexyl acrylate copolymerized with one or more of the following:</p> <p>Acrylonitrile.</p> <p>Itaconic acid.</p> <p>Methacrylonitrile.</p> <p>Methyl acrylate.</p> <p>Methyl methacrylate.</p> <p>4,4'-Isopropylidenediphenolpichlorohydrin average molecular weight 900.</p> <p>Melamine-formaldehyde as the basic polymer or chemically modified with methyl alcohol.</p> <p>Methacrylic acid and its ethyl or methyl esters copolymerized with one or more of the following:</p> <p>Acrylic acid.</p> <p>Ethyl acrylate.</p> <p>Methyl acrylate.</p> <p><math>\alpha</math>-Methyl styrene polymer.</p> <p><math>\alpha</math>-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 <math>\alpha</math>-methylstyrene to 3 vinyltoluene).</p> <p>Petroleum alicyclic hydrocarbon resins .....</p> <p>Polyamide resins (CAS Reg. No. 68139-70-8), as the basic resin, derived from:</p> <p>Dimerized vegetable oil or tall oil acids containing not more than 20 percent of monomer acids.</p> <p>Azelaic acid (CAS Reg. No. 123-99-9) in an amount not to exceed 3.7 percent by weight of the polyamide resin.</p> <p>Ethylenediamine (CAS Reg. No. 107-15-3).</p> <p>Piperazine (CAS Reg. No. 110-85-0) in an amount not to exceed 6.4 percent by weight of the polyamide resin.</p> <p>Polyamide resins, derived from dimerized vegetable oil acids (containing not more than 20% of monomer acids) and ethylenediamine, as the basic resin.</p> <p>Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acids (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin.</p>	<p>For use only as a polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.</p> <p>For use only in coatings that contact food under conditions of use D, E, F, or G described in table 2 of § 176.170(c) of this chapter, provided that the concentration of <math>\alpha</math>-methylstyrene-vinyltoluene copolymer resins in the finished food-contact coating does not exceed 1.0 milligram per square inch of food-contact surface.</p> <p>As defined in § 176.170 of this chapter. Blended with butyl rubber for use as a component of coatings on polyolefin fabric for bulk packaging of raw fruits and vegetables and used at a level not to exceed 30 percent by weight of the total coating solids.</p> <p>For use only in coatings for polypropylene films that contact food at temperatures not to exceed room temperature.</p> <p>For use only in coatings for polyolefin films that contact food at temperatures not to exceed room temperature.</p> <p>For use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.</p>

List of substances	Limitations
<p>Polyester resins formed by reaction of one or more of the following polybasic acids and monobasic acids with one or more of the following polyhydric alcohols:</p> <p>Polybasic acids:</p> <p>Adipic.</p> <p>Azelaic .....</p> <p>Dimerized fatty acids derived from:</p> <p>Animal, marine or vegetable fats and oils.</p> <p>Tall oil.</p> <p>Fumaric.</p> <p>Isophthalic.</p> <p>Maleic.</p> <p>o-Phthalic.</p> <p>Sebacic.</p> <p>Terephthalic.</p> <p>Trimellitic.</p> <p>Monobasic acids:</p> <p>Fatty acids derived from:</p> <p>Animal, marine, or vegetable fats and oils.</p> <p>Gum rosin .....</p> <p>Polyhydric alcohols:</p> <p>1,3-Butylene glycol.</p> <p>Diethylene glycol.</p> <p>2,2-Dimethyl-1,3-propanediol.</p> <p>Dipropylene glycol.</p> <p>Ethylene glycol.</p> <p>Glycerol.</p> <p>Mannitol.</p> <p>α-Methyl glucoside.</p> <p>Pentaerythritol.</p> <p>Propylene glycol.</p> <p>Sorbitol.</p> <p>Trimethylol ethane.</p> <p>Trimethylol propane.</p> <p>Polyethylenimine .....</p> <p>Polystyrene.</p> <p>Polyvinyl acetate.</p> <p>Polyvinyl chloride .....</p> <p>Siloxanes and silicones: platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083–18–1 and CAS Reg. No. 68083–19–2) with methylhydrogen polysiloxane (CAS Reg. No. 63148–57–2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037–59–2). The following substances may be used as optional polymerization inhibitors:</p> <p>3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107–54–0), at a level not to exceed 0.53 weight percent;</p> <p>1-Ethynylcyclohexene (CAS Reg. No. 931–49–7), at a level not to exceed 0.64 weight percent;</p> <p>Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054–10–4), at a level not to exceed 1.0 weight percent;</p> <p>Methylvinyl cyclosiloxane (CAS Reg. No. 68082–23–5); and.</p> <p>Tetramethyltravinylicyclotetrasiloxane (CAS Reg. No. 2554–06–5)..</p>	<p>For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, table 1, under Category VIII, and under conditions of use E, F, or G, described in table 2 of § 176.170(c) of this chapter.</p> <p>As defined in § 178.3870 of this chapter. For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, table 1, under Category VIII, and under conditions of use E, F, or G described in table 2 of § 176.170(c) of this chapter.</p> <p>For use only as a primer subcoat to anchor epoxy surface coatings to the base sheet.</p> <p>Platinum content not to exceed 150 parts per million.</p>

List of substances	Limitations
<p>Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg. No. 624-48-6) and vinyl acetate (CAS Reg. No. 108-05-4) may be used as optional polymerization inhibitors.</p>	<p>Platinum content not to exceed 100 parts per million. For use only as a surface coating under the following conditions:</p> <ol style="list-style-type: none"> <li>1. In coatings for olefin polymers provided the coating contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, II, VI, and VII-B when used under conditions of use E, F, and G described in table 2 in § 176.170(c) of this chapter.</li> <li>2. In coatings for olefin polymers provided the coating contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Types III, IV, V, VII-A, VIII, and IX when used under conditions of use A through H described in table 2 in § 176.170(c) of this chapter.</li> </ol>
<p>Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg. No. 624-48-6), vinyl acetate (CAS Reg. No. 108-05-4), dibutyl maleate (CAS Reg. No. 105-76-0) and diallyl maleate (CAS Reg. No. 999-21-3) may be used as optional polymerization inhibitors. The polymer may also contain C<sub>16</sub>-C<sub>18</sub> olefins (CAS Reg. No. 68855-60-7) as a control release agent.</p> <p>Styrene copolymerized with one or more of the following:</p> <p>Acrylonitrile.</p> <p>α-Methyl styrene.</p> <p>Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M<sub>n</sub>) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent.</p> <p>Styrene-isobutylene copolymer.</p> <p>Terpene resins consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.</p> <p>2-Sulfoethyl methacrylate, sodium salt [Chemical Abstracts Service No. 1804-87-1].</p>	<p>Platinum content not to exceed 100 parts per million. For use only as a release coating for pressure sensitive adhesives.</p>
<p>Vinyl chloride-acetate, hydroxyl-modified copolymer or maleic acid-modified copolymer.</p> <p>Vinyl chloride copolymerized with one or more of the following:</p> <p>Acrylonitrile.</p> <p>Vinyl acetate.</p> <p>Vinylidene chloride.</p> <p>Vinylidene chloride copolymerized with one or more of the following:</p> <p>Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.</p> <p>Acrylonitrile.</p> <p>Itaconic acid.</p> <p>Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.</p> <p>Methacrylonitrile.</p> <p>Vinyl chloride.</p> <p>(ii) Plasticizers:</p> <p>Acetyl tributyl citrate.</p> <p>Acetyl triethyl citrate.</p> <p>Butyl phthalyl butyl glycolate.</p> <p>Butyl stearate.</p> <p>Dibutyl sebacate.</p> <p>Diethyl phthalate.</p> <p>2-Ethylhexyl diphenyl phosphate.</p> <p>Ethyl phthalyl ethyl glycolate.</p> <p>Glycerol monooleate .....</p>	<p>For use only in contact with foods of Types IV-A, V, and VII in table 1 of § 176.170(c) of this chapter, under use conditions E through G in table 2 of § 176.170(c), and with foods of Types VIII and IX without use temperature restriction.</p> <p>For use only in copolymer coatings under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.</p>



List of substances	Limitations
<p>Glycerol triacetate. Triethyl citrate. (iii) Adjuvants (release agents, waxes, and dispersants): Acetone. Amides (unsubstituted) of fatty acids from vegetable or animal oils. <i>n</i>-Butyl acetate. <i>n</i>-Butyl alcohol. Candelilla wax. Carnauba wax. 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172–55–4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682–20–4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935–90–2) and optionally containing magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).. 1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691–65–7). Ethyl acetate. Fatty acids from vegetable or animal oils and their aluminum, ammonium, calcium, magnesium, and sodium salts. Hexane. Methyl ethyl ketone. <i>N,N</i>-Dioleylethylenediamine (CAS Reg. No. 110–31–6) ...</p> <p>Petroleum waxes conforming to specifications included in a regulation in subchapter B of this chapter. Polyvinyl alcohol, minimum viscosity of 4% aqueous solution at 20 °C of 4 centipoises and percent alcoholysis of 87–100.</p> <p>Sodium dioctyl sulfosuccinate. Sodium dodecylbenzenesulfonate. Sodium lauryl sulfate. Sorbitan and sorbitol esters of fatty acids from vegetable or animal oils. Spermaceti wax. Tetrahydrofuran. Toluene.</p> <p>(iv) Preservatives: Silver chloride-coated titanium dioxide .....</p>	<p>For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.</p> <p>For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coating.</p> <p>For use only in ionomeric resins complying with § 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.</p> <p>For use only as a dispersing agent at levels not to exceed 6% of total coating weight in coatings for polyolefin films provided the finished polyolefin films contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types V, VIII, and IX.</p> <p>For use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.</p>

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface.

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

the provisions of § 180.22 of this chapter.

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

**§ 175.350 Vinyl acetate/crotonic acid copolymer.**

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

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

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

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

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

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

(1) Substances generally recognized as safe in food.

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

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

List of substances	Limitations
Silica. Japan wax.	

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

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

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

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

#### § 175.360 Vinylidene chloride copolymer coatings for nylon film.

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

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

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

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

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface when tested by the methods described in §176.170(d) of this chapter.

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

## § 175.365

the provisions of §180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 43 FR 7206, Feb. 21, 1978; 45 FR 76998, Nov. 21, 1980; 47 FR 54430, Dec. 3, 1982]

### § 175.365 Vinylidene chloride copolymer coatings for polycarbonate film.

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

(a) The coating is applied as a continuous film over one or both sides of a base film produced from polycarbonate resins complying with §177.1580 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with acrylonitrile, methyl acrylate, and acrylic acid. The finished copolymers contain at least 50 weight-percent of polymer units derived from vinylidene chloride.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate in addition to substances described in §174.5(d) of this chapter.

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under 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, shall yield net chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of coated surface as determined by the methods described in §176.170(d) of this chapter. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

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

## 21 CFR Ch. I (4-1-16 Edition)

### § 175.380 Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.

The resins identified in paragraph (a) of this section may be safely used as a food-contact coating for articles intended for use in contact with food, in accordance with the following prescribed conditions.

(a) The resins are produced by the condensation of xylene-formaldehyde resin and 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins, to which may have been added certain optional adjuvant substances required in the production of the resins or added to impart desired physical and technical properties. The optional adjuvant substances may include resins produced by the condensation of allyl ether of mono-, di-, or trimethylol phenol and capryl alcohol and also may include substances identified in §175.300(b)(3), with the exception of paragraph (b)(3)(xxxi) and (xxxii) of that section.

(b) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed 160 °F with food of Types I, II, VI-A and B, and VIII described in table 1 of §176.170(c) of this chapter provided that the coating in the finished form in which it is to contact food meets the following extractives limitations when tested by the methods provided in §175.300(e):

(1) The coating when extracted with distilled water at 180 °F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 8 percent (by volume) ethyl alcohol in distilled water at 160 °F for 4 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(c) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed room temperature with food of Type VI-C described in table 1 of §176.170(c) of this chapter provided the coating in the finished form in which it is to contact food meets the following

## Food and Drug Administration, HHS

## § 176.110

extractives limitations when tested by the methods provided in § 175.300(e):

(1) The coating when extracted with distilled water at 180 °F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 50 percent (by volume) ethyl alcohol in distilled water at 180 °F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch.

### § 175.390 Zinc-silicon dioxide matrix coatings.

Zinc-silicon dioxide matrix coatings may be safely used as the food-contact surface 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 coating is applied to a metal surface, cured, and washed with water to remove soluble substances.

(b) The coatings are formulated from optional substances which include:

(1) Substances generally recognized as safe.

(2) Substances for which safe conditions of use have been prescribed in § 175.300.

(3) Substances identified in paragraph (c) of this section, subject to the limitations prescribed.

(c) The optional substances permitted are as follows:

List of substances	Limitations
Ethylene glycol .....	As a solvent removed by water washing.
Iron oxide.	
Lithium hydroxide .....	Removed by water washing.
Methyl orange .....	As an acid-base indicator.
Potassium dichromate .....	Removed by water washing.
Silica gel.	
Sodium silicate.	
Zinc, as particulate metal.	

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under the conditions of its intended use as shown in table 1 and 2 of § 175.300(d) (using 20 percent alcohol as the solvent when the type of food contains approximately 20 percent alcohol) shall yield total extractives not to exceed those prescribed in § 175.300(c)(3); lithium ex-

tractives not to exceed 0.025 milligram per square inch of surface; and chromium extractives not to exceed 0.05 microgram per square inch of surface.

(e) The coatings are used as food-contact surfaces for bulk reusable containers intended for storing, handling, and transporting food.

## PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

### Subpart A [Reserved]

### Subpart B—Substances for Use Only as Components of Paper and Paperboard

Sec.

- 176.110 Acrylamide-acrylic acid resins.
- 176.120 Alkyl ketene dimers.
- 176.130 Anti-offset substances.
- 176.150 Chelating agents used in the manufacture of paper and paperboard.
- 176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.
- 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
- 176.180 Components of paper and paperboard in contact with dry food.
- 176.200 Defoaming agents used in coatings.
- 176.210 Defoaming agents used in the manufacture of paper and paperboard.
- 176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.
- 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.
- 176.260 Pulp from reclaimed fiber.
- 176.300 Slimicides.
- 176.320 Sodium nitrate-urea complex.
- 176.350 Tamarind seed kernel powder.

AUTHORITY: 21 U.S.C. 321, 342, 346, 348, 379e.

SOURCE: 42 FR 14554, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 176 appear at 61 FR 14482, Apr. 2, 1996, 66 FR 56035, Nov. 6, 2001, and 70 FR 72074, Dec. 1, 2005.

### Subpart A [Reserved]

### Subpart B—Substances for Use Only as Components of Paper and Paperboard

#### § 176.110 Acrylamide-acrylic acid resins.

Acrylamide-acrylic acid resins may be safely used as components of articles intended for use in producing,