

§ 175.300

21 CFR Ch. I (4-1-01 Edition)

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.

(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.

α -Methyl glucoside.

Pentaerythritol.

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.

§ 175.300

21 CFR Ch. I (4-1-01 Edition)

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 C₁₀-C₁₆)-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C₁₀ carbon atoms and a minimum of 48 percent C₁₂ carbon atoms and a minimum of 18 percent C₁₄ 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.

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.
- Isophthaly 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 alcoholic 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 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

§ 175.300

21 CFR Ch. I (4-1-01 Edition)

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.

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.

Food and Drug Administration, HHS

§ 175.300

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.

(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.

α -Methyl styrene polymer.

Styrene copolymerized with one or more of the following:

Acrylonitrile.

α -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, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(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.

§ 175.300

21 CFR Ch. I (4-1-01 Edition)

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}° (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.

(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'-Dioleylethylenediamine (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 ethylenediamine.
 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.
 Dioctyl 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
 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, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to

§ 175.300

21 CFR Ch. I (4-1-01 Edition)

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.

(xxxi) 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.

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*lilon-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.

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, re-

spectively, 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, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. For use only 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 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 THE 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 ^{1 2} (time and temperature)	8 percent alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV-B	250 °F, 2 hrdodo
B. Boiling water sterilized	III, IV-A, VIIdo	150 °F, 2 hr.do
	II	212 °F, 30 mindodo
C. Hot filled or pasteurized above 150 °F.	III, VIIdo	120 °F, 30 min.do
	II, IV-B	Fill boiling, cool to 100 °F.dodo
	III, IV-Adododo
	Vdo	120 °F, 15 min.do
D. Hot filled or pasteurized below 150 °F.	II, IV-B, VI-B	150 °F, 2 hrdo	150 °F, 2 hr
	III, IV-Ado	100 °F, 30 min.do
	Vdododo
	VI-Adododo
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV-B, VI-B	120 °F, 24 hrdo	120 °F, 24 hr
	III, IV-Ado	70 °F, 30 min.do
	V, VIIdododo
	VI-Adododo
F. Refrigerated storage, no thermal treatment in the container).	I, II, III, IV-A, IV-B, VI-B, VII.	70 °F, 48 hrdo	70 °F, 48 hr
	VI-Adododo
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII	70 °F, 24 hrdodo
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.dodo
2. Aqueous, high or low free oil or fat.	III, IV-A, VIIdo	120 °F, 30 min.do

¹ Heptane extractant not to be used on wax-lined containers.

² 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-3/4-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 tem-

perature 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 ¼-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 ¼-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 ¼-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 ex-

tractives 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.* Pre-heat 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.* Pre-heat 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 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".

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.*

