[¶ 56,813] Polyethylene glycol (mean molecular weight 200-9,500)

§ 121.2513 Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

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

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in § 121.1185(b).

(c) The provisions of paragraph (b) of this section are not applicable to polyethylene glycols used in food-packaging adhesives complying with § 121.2520.

[*As added*, 33 *F. R.* 15282, *effective October* 15, 1968.]

[¶ 56,814] Resinous and polymeric coatings

§ 121.2514 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:

[¶ 56,815]

(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.

[¶ 56,816]

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

[¶ 56,817]

(1) Substances generally recognized as safe in food.

[¶ 56,818]

(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.

[¶ 56,819]

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

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[¶ 56,820]

(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.
Oiticia.
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.

[¶ 56,821]

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in subdivision (i) of this subparagraph to form esters with:

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

[¶ 56,822]

(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.

[¶ 56,823]

(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.

[¶ 56,824]

(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 ((v) (*a*) of this subparagraph) with:

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

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(c) Rosin esters ((v)(b) of this subparagraph) modified by reaction with:

Maleic anhydride.
o-, *m-*, and *p*-substituted phenol-formaldehydes listed in subdivision (vi) of this subparagraph.
Phenol-formaldehyde.

(d) Rosin salts:

Calcium resinate (limed rosin).
Zinc resinate.

[¶ 56,825]

(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.

[¶ 56,826]

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

(a) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in subdivision (i) of this subparagraph.
Diphenolic acid.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Sebacic.
Terephthalic.
Terpene-maleic acid adduct.
Trimellitic.

(b) Monobasic acids:

Benzoic acid.
tert-Butyl benzoic acid.
Fatty acids derived from oils listed in subdivision (i) of this subparagraph.
Rosins listed in subdivision (v)(a) of this subparagraph, for use only as reactants in oil-based or fatty acid-based alkyd resins.

[¶ 56,826 continues on page 55,923-3.]

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(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.
Trimethylol ethane.
Trimethylol propane.

(d) Monohydric alcohols:

Cetyl alcohol.
Decyl alcohol.
Lauryl alcohol.
Myristyl alcohol.
Octyl alcohol.
Stearyl alcohol.

[¶ 56,827]

(viii) Epoxy resins, catalysts, and adjuncts:

(a) Epoxy resins, as the basic polymer:

(Alkoxy C_{10}-C_{16})-2,3-epoxypropane, in which the alkyl groups consist of a maximum of 1 percent C_{10} carbon atoms and a minimum of 48 percent C_{12} carbon atoms and a minimum of 18 percent C_{14} 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 subdivision (i) of this subparagraph.

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 phenol-novolak resins with epichlorohydrin.

4,4'-Isopropylidenediphenol - epichlorohydrin.

4,4'-Isopropylidenediphenol - epichlorohydrin reacted with one or more the drying oils or fatty acids listed in subdivision (i) of this subparagraph.

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.
Phenol-formaldehyde.
Urea-formaldehyde.

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

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.

Diphenylamine.

Diethylenetriamine.

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.

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.

Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gal-

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lons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

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.

(*c*) Adjuncts for epoxy resins:

Aluminum butylate.

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 subdivision (xxii) (*b*) of this subparagraph (3), for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

Triethylenetetramine.

Polyamides from dimerized vegetable oils and the amine catalysts listed in (*b*) of this subdivision, as the basic polymer.

[¶ 56,828]

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

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[¶ 56,829]

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

[¶ 56,830]

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

Dipentine.
α-Pinene.
β-Pinene.

[¶ 56,831]

(xii) Urea-formaldehyde, as the basic polymer:

Urea-formaldehyde.
Urea-formaldehyde chemically modified with methyl, ethyl, butyl, propyl, isopropyl, or isobutyl alcohol.
Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in subdivision (viii) (*b*) of this subparagraph.

[¶ 56,832]

(xiii) 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 subdivision (viii) (*b*) of this subparagraph.
Dimethylamine-2-methyl-1-propanol.
Methylpropanolamine.
Triethanolamine.
Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

[¶ 56,833]

(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.

[¶ 56,834]

(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, hydroxyl-modified copolymer.
Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.
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 [copolymer].
Vinyl acetate.
Vinylidene chloride.

[¶ 56,835]

(xvi) Celiulosics, as the basic polymers:

Carboxymethylcellulose.
Cellulose acetate.
Celiulose acetate-butyrate.
Cellulose acetate-propionate.
Ethylcellulose.
Ethyl hydroxyethylcellulose.

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Hydroxyethylcellulose.
Hydroxypropyl methylcellulose.
Methylcellulose.
Nitrocellulose.

[¶ 56,836]

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.
α-Methyl styrene polymer.
Styrene copolymerized with one or more of the following:
Acrylonitrile.
α-Methyl-styrene.

[¶ 56,837]

(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.

[¶ 56,838]

(xix) Polypropylene as the basic polymer:

Polypropylene.
Maleic anhydride adduct of polypropylene. The polypropylene used in the manufacture of the adduct complies with § 121.2501 (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 available on request from the Commissioner of Food and Drugs.

[¶ 56,839]

(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 acidhydroxyethyl 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 and that are intended for contact, under condition of use D, E, F, or G described in table 2 of § 121.2514(d), 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 subdivision (viii) (*a*) of this subparagraph.
Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in subdivision (viii)(*a*) of this subparagraph.
2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in subdivision (viii) of this subparagraph.
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.

[¶ 56,840]

(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.

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[¶ 56,841]

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

(*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.

[¶ 56,842]

(xxiii) Waxes:

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

[¶ 56,843]

(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-Xenoxyl)-1,2-epoxypropane.

[¶ 56,844]

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

N,N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acide 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.

[¶ 56,845]

(xxvi) Pigments and colorants:

Aluminum.
Aluminum hydrate.
Aluminum and potassium silicate (mica).
Aluminum mono-, di-, tristearate.
Aluminum silicate (china clay).
Barium sulfate.
Bentonite.
Bentonite, modified with dimethyl dioctadecyl ammonium ion.
Burnt umber.

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Calcium carbonate.
Calcium silicate.
Calcium sulfate.
Carbon black (channel process).
Cobalt oxide-aluminum oxide.
Diatomaceous earth.
Iron oxides.
Magnesium oxide.
Magnesium silicate (talc).
Raw sienna.
Phthalocyanine blue (C. I. pigment blue 15, C. I. No. 74160).
Silica.
Tartrazine lake (certified FDC Yellow No. 5 only).
Titanium dioxide.
Titanium dioxide-barium sulfate.
Titanium dioxide-magnesium silicate.
Zinc carbonate.
Zinc oxide.

[¶ 56,846]

(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.

[¶ 56,847]

(xxviii) Silicones and their curing catalysts:

(*a*) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(*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.

[¶ 56,848]

(xxix) Surface active agents:

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 D 1243-60), 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 dodecyl benzenesulfonate.
Sodium lauryl sulfate.

[¶ 56,849]

(xxx) Antioxidants:

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

[¶ 56,850]

(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 § 121.2550(b)(5), the following may be used:

Butadiene-styrene-fumaric acid copolymer.
4,4'-Butylidenebis(6-*tert*-butyl-*m*-cresol).
Dibenzamido phenyl disulfide.
Di-β-naphthyl phenylenediamine.

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Dipentamethylene thiuram tetrasulfide.

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.

Tetrasodium EDTA (tetrasodium ethylenediaminetetraacetate).

Tri (mixed mono- and dinonylphenyl) phosphite.

Zinc dibutyldithiocarbamate.

[¶ 56,851]

(xxxii) *Side seam cements.* In addition to the substances listed in subdivisions (i) to (xxx), inclusive, of this subparagraph, the following may be used:

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

ε-Caprolactam-(ethylene-ethyl acrylate) graft-polymer

Dicumyl peroxide for use only as polymerization catalyst.

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.

Ethyl toluene sulfonamide.

Polyamides derived from the following acids and amines:

Acids:
- Adipic.
- Sebacic.
- Vegetable oil acids (with or without dimerization).

Amines:
- Diethylenetriamine.
- Diphenylamine.
- Ethylenediamine.
- Hexamethylenediamine.
- Tetraethylenepentamine.
- Triethylenetetramine.

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.

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.

[¶ 56,852]

(xxxiii) Miscellaneous materials:

Ammonium citrate.

Ammonium potassium phosphate.

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.

Cetyl alcohol.

Decyl alcohol.

Disodium hydrogen phosphate.

Ethyl acetoacetate.

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 § 121.2511.

Poly (ethylene oxide)

Sodium pyrophosphate.

Stannous chloride.

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Stannous stearate.

Stannous sulfate.

Stearyl alcohol.

Tetrasodium pyrophosphate.

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

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.

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[¶ 56,853]

(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.

[¶ 56,854]

(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.

[¶ 56,855]

(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 subparagraph, 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.

[¶ 56,856]

(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.

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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).

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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	Heptane [1] [2]	8% alcohol
		Time and temperature	*Time and temperature*	*Time and temperature*
A. High temperature heat-sterilized (e.g., over 212° F.).	I, IV-B	250° F., 2 hr.		
	III, IV-A, VII	250° F., 2 hr.	150° F., 2 hr.	
B. Boiling water sterilized...	II	212° F., 30 min.		
	III, VII	212° F., 30 min.	120° F., 30 min.	
C. Hot filled or pasteurized above 150° F.	II, IV-B	Fill boiling, cool to 100° F.		
	III, IV-A	Fill boiling, cool to 100° F.	120° F., 15 min.	
	V		120° F., 15 min.	
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B	150° F., 2 hr.		
	III, IV-A	150° F., 2 hr.	100° F., 30 min.	
	V		100° F., 30 min.	
	VI-A			150° F., 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV-B, VI-B	120° F., 24 hr.		
	III, IV-A	120° F., 24 hr.	70° F., 30 min.	
	V, VII		70° F., 30 min.	
	VI-A			120° F., 24 hr.
F. Refrigerated storage (no thermal treatment in the container).	I, II, III, IV-A, IV-B, VI-B, VII.	70° F., 48 hr.		
	VI-A			70° F., 48 hr.
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	212° F., 30 min.	120° F., 30 min.	

[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.

[¶ 56,857]

(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

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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 ⅛-inch—¼-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 ¼-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 subparagraph (5) of this paragraph.

(ii) *Water (212° F. for 30 minutes), simulating boiling water sterilization.* Fill the container 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 subparagraph (5) of this paragraph.

(iii) *Water (from boiling to 100° F.), simulating hot fill or pasteurization above 150° F.* Fill the container within ¼-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 subparagraph (5) of this paragraph.

(iv) *Water (150° F. 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

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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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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,

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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 subparagraph (5) of this paragraph.

(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 mininmize 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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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

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flask or beaker. Proceed with the determination of the amount of extractives by the method described in subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

(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 subparagraph (5) of this paragraph.

NOTE: The tests specified in subparagraph (4)(i) through (xvii) of paragraph (e) 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 subparagraph (4)(i) to (xvii), inclusive, of this paragraph 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

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in the extraction procedure, and evaporate to a few milliliters on a nonsparking 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.*

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

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

(*b*) *Heptane.*

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

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

Where:

e = Extractives residue in parts per million for any container size.
Ex = 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 extractives residue.
e' or ee' is substituted for e in the above formulas when necessary.

If when calculated by the formulas in (*a*) and (*b*) of this subdivision, 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 subdivision (ii) of this subparagraph (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 subdivision (i) of this subparagraph. 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-

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temperature hot plate. 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 (*é*). This *é* is substituted for *c* in the equations in (*a*) and (*b*) of subdivision (i) of this subparagraph. 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 (*é*) to obtain the zinc-corrected chloroform-soluble extractives residue (*eé*). This *eé* is substituted for *e* in the formulas in (*a*) and (*b*) of subdivision (i) of this subparagraph. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for 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.

[¶ 56,858]

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

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a ⅛-inch-¼-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 x 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" x 19" x 19", constant temperature to ± 2° F. (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" x 19" x 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" x 19" x 19".

Hot plate, nonsparking (explosion proof), top 12" x 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.

[¶ 56,859]

(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.

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[*As amended*, 31 *F. R.* 2897, *effective February* 18, 1966; 31 *F. R.* 9106, *effective July* 2, 1966; 31 *F. R.* 10575, *effective August* 6, 1966; 31 *F. R.* 13474, *effective October* 19, 1966; 31 *F. R.* 15570, *effective December* 10, 1966; 32 *F. R.* 5675, *effective April* 7, 1967; 32 *F. R.* 6132, *effective April* 19, 1967; 32 *F. R.* 6568, *effective April* 28, 1967, 32 *F. R.* 7264, *effective May* 16 1967; 32 *F. R.* 11522, *effective August* 10, 1967; 32 *F. R.* 18096, *effective December* 19, 1967; 33 *F. R.* 568, *effective January* 17, 1968; 33 *F. R.* 15282, *effective October* 15, 1968; 33 *F. R.* 15654, *effective October* 23, 1968; 33 *F. R.* 16272, *effective November* 6, 1968; 33 *F. R.* 17902, *effective December* 3, 1968; 33 *F. R.* 18372, *effective December* 11, 1968; 34 *F. R.* 5838, *effective March* 28, 1969; 34 *F. R.* 6684, *effective April* 19, 1969; 34 *F. R.* 13274, *effective August* 15, 1969; 34 *F. R.* 20426, *effective December* 31, 1969; 35 *F. R.* 8552, *effective June* 3, 1970; 35 *F. R.* 16631, *effective October* 27, 1970; 37 *F. R.* 4712, *effective March* 4, 1972; 37 *F. R.* 6052, *effective March* 24, 1972.]

[¶ 56,865] Chelating agents used in the manufacture of paper and paperboard

§ 121.2515 The substances named in paragraph (a) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

(a) Chelating agents:

List of substances:	*Limitations*
Ammonium fructoheptonate	.....
Ammonium glucoheptonate	.....
Disodium ethylenediamine tetraacetate	.....
Pentasodium salt of diethylenetriamine pentaacetate	.....
Sodium fructoheptonate	.....
Sodium glucoheptonate	.....
Tetrasodium ethylenediamine tetraacetate	.....
Trisodium *N*-hydroxyethyl ethylenediamine triacetate	.....

(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

[¶ 56,866] Sodium nitrate-urea complex

§ 121.2516 Sodium nitrate-urea complex may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Sodium nitrate-urea complex is a clathrate of approximately two parts urea and one part sodium nitrate.

(b) Sodium nitrate-urea complex conforming to the limitations prescribed in subparagraph (1) of this paragraph is used as provided in subparagraph (2) of this paragraph.

(1) *Limitations.* (i) It is used as a plasticizer in glassine and greaseproof paper.

(ii) The amount used does not exceed that required to accomplish its intended technical effect or exceed 15 percent by weight of the finished paper.

(2) *Conditions of use.* The glassine and greaseproof papers are used for packaging dry food or as the food-contact surface for dry food.

[¶ 56,867] Polyethylene, oxidized

§ 121.2517 Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum [illegible]

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