

and cooled to room temperature. A sample of the extracting solvent is then withdrawn and analyzed for acrylonitrile monomer by a gas chromatographic method titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies, are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

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

(g) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48544, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982; 54 FR 24898, June 12, 1989]

§ 177.1060 *n*-Alkylglutarimide/acrylic copolymers.

n-Alkylglutarimide/acrylic copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and part 174 of this chapter.

(a) *Identity*. For the purpose of this section, *n*-alkylglutarimide/acrylic copolymers are copolymers obtained by reaction of substances permitted by §177.1010(a) (1), (2), and (3) with the following substance: Monomethylamine (CAS Reg. No. 74-89-5), to form *n*-methylglutarimide/acrylic copolymers.

(b) *Adjuvants*. The copolymers identified in paragraph (a) of this section may contain adjuvant substances required in their production. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for

such use by applicable regulations, as set forth in part 174 of this chapter.

(c) *Specifications*. Maximum nitrogen content of the copolymer determined by micro-Kjeldahl analysis, shall not exceed 8 percent.

(d) *Limitations*. (1) The *n*-alkylglutarimide/acrylic copolymers in the finished form in which they shall contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature described in tables 1 and 2 of §176.170(c) of this chapter, shall yield extractives not to exceed the limitations of §177.1010(b) of this chapter, when prepared as strips, as described in §177.1010(c)(2) of this chapter.

(2) The *n*-alkylglutarimide/acrylic copolymers shall not be used as polymer modifiers in vinyl chloride homo- or copolymers.

(e) *Conditions of use*. The *n*-alkylglutarimide/acrylic copolymers are used as articles or components of articles (other than articles composed of vinyl chloride homo- or copolymers) intended for use in contact with all foods except beverages containing more than 8 percent alcohol under conditions of use D, E, F, and G as described in table 2 of §176.170(c) of this chapter.

[54 FR 20382, May 11, 1989, as amended at 58 FR 17098, Apr. 1, 1993]

§ 177.1200 Cellophane.

Cellophane may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in §181.22 of this chapter.

§ 177.1200

21 CFR Ch. I (4-1-07 Edition)

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of cellophane.

(4) Substances named in this section and further identified as required.

(c) *List of substances:*

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Acrylonitrile-butadiene copolymer resins	As the basic polymer.
Acrylonitrile-butadiene-styrene copolymer resins	Do.
Acrylonitrile-styrene copolymer resins	Do.
Acrylonitrile-vinyl chloride copolymer resins	Do.
N-Acyl sarcosines where the acyl group is lauroyl or stearyl ...	For use only as release agents in coatings at levels not to exceed a total of 0.3 percent by weight of the finished packaging cellophane.
Alkyl ketene dimers identified in § 176.120 of this chapter.	
Aluminum hydroxide.	
Aluminum silicate.	
Ammonium persulfate.	
Ammonium sulfate.	
Behenamide.	
Butadiene-styrene copolymer	As the basic polymer.
1,3-Butanediol.	
<i>n</i> -Butyl acetate	0.1 percent.
<i>n</i> -Butyl alcohol	Do.
Calcium ethyl acetoacetate.	
Calcium stearoyl-2-lactylate identified in § 172.844 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Carboxymethyl hydroxyethylcellulose polymer.	
Castor oil, hydrogenated.	
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester.	As the basic polymer.
Castor oil phthalate, hydrogenated	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Castor oil, sulfonated, sodium salt.	
Cellulose acetate butyrate.	
Cellulose acetate propionate.	
Cetyl alcohol.	
Clay, natural.	
Coconut oil fatty acid (C ₁₂ -C ₁₈) diethanolamide, coconut oil fatty acid (C ₁₂ -C ₁₈) diethanolamine soap, and diethanolamine mixture having total alkali (calculated as potassium hydroxide) of 16-18% and having an acid number of 25-35.	For use only as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Copal resin, heat processed	As basic resin.
Damar resin.	
Defoaming agents identified in § 176.200 of this chapter.	
Dialkyl ketones where the alkyl groups are lauryl or stearyl	Not to exceed a total of 0.35 percent.
Dibutylphthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent. Do.
Dicyclohexyl phthalate	
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Di(2-ethylhexyl) adipate.	
Di(2-ethylhexyl) phthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent. Do. Do.
Diisobutyl phthalate	Do.
Dimethylcyclohexyl phthalate	Do.
Dimethyldialkyl (C ₈ -C ₁₈) ammonium chloride	0.005 percent for use only as a flocculant for slip agents.
Di- <i>n</i> -ocyltin bis (2-ethylhexyl maleate)	For use only as a stabilizer at a level not to exceed 0.55 percent by weight of the coating solids in vinylidene chloride copolymer waterproof coatings prepared from vinylidene chloride copolymers identified in this paragraph, provided that such vinylidene chloride copolymers contain not less than 90 percent by weight of polymer units derived from vinylidene chloride.

Food and Drug Administration, HHS

§ 177.1200

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
<p>N,N'-Dioleoyethylenediamine, N,N'-dilinoleoyethylenediamine and N-oleoyl-N'linoleoyethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°–228 °F., as determined by ASTM method D127–60 ("Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax" (Revised 1960), which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), and an acid value of 10 maximum.</p>	<p>0.5 percent.</p>
<p>N,N'-Dioleoyethylenediamine (N,N'-ethylenebisoleamide). Disodium EDTA. Distearic acid ester of di(hydroxyethyl) diethylenetriamine monoacetate.</p>	<p>0.06 percent.</p>
<p>N,N'-Distearoyethylenediamine (N,N'-ethylenebis stearamide). Epoxidized polybutadiene</p>	<p>For use only as a primer subcoat to anchor surface coatings to the base sheet.</p>
<p>Erucamide. Ethyl acetate. Ethylene-vinyl acetate copolymers complying with § 177.1350. 2-Ethylhexyl alcohol</p>	<p>0.1 percent for use only as lubricant.</p>
<p>Fatty acids derived from animal and vegetable fats and oils, and the following salts of such acids, single or mixed: Aluminum, ammonium, calcium, magnesium, potassium, sodium. Ferrous ammonium sulfate. Fumaric acid.</p>	<p>As the basic polymer.</p>
<p>Glycerin-maleic anhydride</p>	<p>As the basic polymer.</p>
<p>Glycerol diacetate. Glycerol monoacetate. Hydroxyethyl cellulose, water-insoluble. Hydroxypropyl cellulose identified in § 172.870 of this chapter. Isopropyl acetate</p>	<p>Residue limit 0.1 percent Do.</p>
<p>Isopropyl alcohol</p>	<p>Do.</p>
<p>Itaconic acid. Lanolin. Lauryl alcohol. Lauryl sulfate salts: ammonium, magnesium, potassium, sodium.</p>	<p>1 percent.</p>
<p>Maleic acid</p>	<p>1 percent.</p>
<p>Maleic acid adduct of butadienestyrene copolymer. Melamine formaldehyde</p>	<p>As the basic polymer.</p>
<p>Melamine-formaldehyde modified with one or more of the following: Butyl alcohol, diaminopropane, diethylenetriamine, ethyl alcohol, guanidine, imino-bis-butylamine, imino-bis-ethylamine, imino-bis-propylamine, methyl alcohol, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane, sulfanilic acid, tetraethylenepentamine, triethanolamine, triethylenetetramine.</p>	<p>As the basic polymer, and used as a resin to anchor coatings to substrate.</p>
<p>Methyl ethyl ketone</p>	<p>Residue limit 0.1 percent</p>
<p>Methyl hydrogen siloxane</p>	<p>0.1 percent as the basic polymer.</p>
<p>α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1α-methylstyrene to 3 vinyltoluene).</p>	<p>0.1 percent as the basic polymer.</p>
<p>Mineral oil, white.</p>	<p>0.1 percent as the basic polymer.</p>
<p>Mono- and bis-(octadecyldiethylene oxide) phosphates (CAS Reg. No. 62362–49–6).</p>	<p>For use only as a release agent at a level not to exceed 0.6 percent by weight of coatings for cellophane.</p>
<p>Naphthalenesulfonic acid-formaldehyde condensate, sodium salt.</p>	<p>0.1 percent, for use only as an emulsifier.</p>
<p>Nitrocellulose, 10.9 percent–12.2 percent nitrogen.</p>	<p>0.1 percent, for use only as an emulsifier.</p>
<p>Nylon resins complying with § 177.1500. n-Octyl alcohol</p>	<p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p>
<p>Olefin copolymers complying with § 177.1520.</p>	<p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p>
<p>Oleic acid reacted with N-alkyl trimethylenediamine (alkyl C₁₆ to C₁₈).</p>	<p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p>
<p>Oleic acid, sulfonated, sodium salt.</p>	<p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p>
<p>Oleyl palmitamide.</p>	<p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p>

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
<i>N,N</i> -Oleoyl-stearylethylenediamine (N-(2-stearoyl-aminoethyl)oleamide).	
Paraffin, synthetic, complying with § 175.250 of this chapter.	
Pentaerythritol tetrastearate	0.1 percent.
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 cellophane coatings that contact food at temperatures not to exceed room temperature.
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 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 polyamido resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.
Polybutadiene resin (molecular weight range 2,000–10,200; bromine number range 210–320).	For use only as an adjuvant in vinylidene chloride copolymer coatings.
Polycarbonate resins complying with § 177.1580.	
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride, and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70 °C–92 °C, and a color of K or paler.	
Polyethylene.	
Polyethyleneaminostearamide ethyl sulfate produced when stearic acid is made to react with equal parts of diethylenetriamine and triethylenetetramine and the reaction product is quaternized with diethyl sulfate.	0.1 percent.
Polyethylene glycol (400) monolaurate.	
Polyethylene glycol (600) monolaurate.	
Polyethylene glycol (400) monooleate.	
Polyethylene glycol (600) monooleate.	
Polyethylene glycol (400) monostearate.	
Polyethylene glycol (600) monostearate.	
Polyethylene, oxidized: complying with the identity prescribed in § 177.1620(a).	
Polyethylenimine	As the basic polymer, for use as a resin to anchor coatings to the substrate and for use as an impregnant in the food-contact surface of regenerated cellulose sheet in an amount not to exceed that required to improve heat-sealable bonding between coated and uncoated sides of cellophane.
Polyisobutylene complying with § 177.1420.	
Polyoxypropylene-polyoxyethylene block polymers (molecular weight 1,900–9,000).	For use as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Polypropylene complying with § 177.1520.	
Polystyrene	As the basic polymer.
Polyvinyl acetate	Do.
Polyvinyl alcohol (minimum viscosity of 4 percent aqueous solution at 20 °C of 4 centipoises).	
Polyvinyl chloride	As the basic polymer.
Polyvinyl stearate	Do.
<i>n</i> -Propyl acetate	Residue limit 0.1 percent.
<i>n</i> -Propyl alcohol	Do.
Rapeseed oil, blown.	
Rosins and rosin derivatives as provided in § 178.3870 of this chapter.	
Rubber, natural (natural latex solids).	
Silica.	
Silicic acid.	
Sodium <i>m</i> -bisulfite.	
Sodium dioctyl sulfosuccinate.	
Sodium dodecylbenzenesulfonate.	
Sodium lauroyl sarcosinate	0.35 percent; for use only in vinylidene chloride copolymer coatings.
Sodium oleyl sulfate-sodium cetyl sulfate mixture	For use only as an emulsifier for coatings; limit 0.005 percent where coating is applied to one side only and 0.01 percent where coating is applied to both sides.
Sodium silicate.	
Sodium stearoyl-2-lactylate identified in § 172.846 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Sodium sulfate.	
Sodium sulfite.	
Spermaceti wax.	
Stannous oleate.	

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
2-Stearamido-ethyl stearate. Stearyl alcohol. Styrene-maleic anhydride resins Terpene resins identified in § 172.615 of this chapter. Tetrahydrofuran Titanium dioxide. Toluene Toluene sulfonamide formaldehyde Triethylene glycol. Triethylene glycol diacetate, prepared from triethylene glycol containing not more than 0.1 percent of diethylene glycol. 2,2,4-Trimethyl-1,3 pentanediol diisobutyrate	As the basic polymer. Residue limit of 0.1 percent. Residue limit of 0.1 percent. 0.6 percent as the basic polymer. For use only in cellophane coatings and limited to use at a level not to exceed 10 percent by weight of the coating solids except when used as provided in §178.3740 of this chapter
Urea (carbamide). Urea formaldehyde Urea formaldehyde modified with methanol, ethanol, butanol diethylenetriamine, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulfite, sulfanilic acid, imino-bis-ethylamine, imino-bis-propylamine, imino-bis-butylamine, diaminopropane, diaminobutane, aminomethylsulfonic acid, polyamines made by reacting ethylenediamine or trimethylenediamine with dichlorethane or dichloropropane. Vinyl acetate-vinyl chloride copolymer resins Vinyl acetate-vinyl chloride-maleic acid copolymer resins Vinylidene chloride copolymerized with one or more of the following: Acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, 2-ethylhexyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride. Vinylidene chloride-methacrylate decyloctyl copolymer Wax, petroleum, complying with § 178.3710 of this chapter.	As the basic polymer. As the basic polymer, and used as a resin to anchor coatings to the substrate. As the basic polymer. Do. Do. Do.

(d) Any optional component listed in this section covered by a specific food additive regulation must meet any specifications in that regulation.

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

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11842, Mar. 19, 1982; 64 FR 57978, Oct. 28, 1999]

§ 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations

in parts 174, 175, 176, 177, 178 and §179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and over-all discs are formulated from substances identified in §175.300(b) of this chapter, with the exception of paragraph (b)(3) (v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or technical effect and in conformance