

§ 176.180

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

soluble extracts which contain high melting waxes (melting point greater than 170 °F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1-0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), table 1 under Category VIII.

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §176.170, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

**§ 176.180 Components of paper and paperboard in contact with dry food.**

The substances listed in this section may be safely used as components of the uncoated or coated food-contact

surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in §176.170(c), table 1, under Type VIII, subject to the provisions of this section.

(a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.

(b) The substances permitted to be used include the following:

(1) Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

(2) Substances identified in the following list:

List of substances	Limitations
Acrylamide polymer with sodium 2-acrylamido-2-methylpropane-sulfonate (CAS Reg. No. 38193-60-1).	For use at a level not to exceed 0.015 weight percent of dry fiber.
(2-Alkenyl) succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 percent C <sub>30</sub> and higher groups (CAS Reg. No. 70983-55-0)..	
4-[2-[2-(2-Alkoxy(C <sub>12</sub> -C <sub>15</sub> ) ethoxy) ethoxy]ethyl]disodium sulfosuccinate.	For use as a polymerization emulsifier and latex emulsion stabilizer at levels not to exceed 5 percent by weight of total emulsion solids.
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C <sub>10</sub> -C <sub>18</sub> with not less than 50 percent C <sub>14</sub> -C <sub>16</sub> )..	
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	Colorant.
Ammonium nitrate..	
Amylose..	
Barium metaborate .....	For use as preservative in coatings and sizings.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5) .....	For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.02 mg/in <sup>2</sup> (0.0031 mg/cm <sup>2</sup> ) of finished paper and paperboard.
<i>N,N</i> -Bis(hydroxyethyl)lauramide.	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064-70-8 .....	For use only as a preservative in coatings.
Borax .....	For use as preservative in coatings.
Boric acid .....	Do.
Butanedioic acid, sulfo-1,4-di-(C <sub>8</sub> -C <sub>11</sub> alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9])..	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.
<i>sec</i> -Butyl alcohol..	
Butyl benzyl phthalate..	
Candelilla wax..	
Carbon tetrachloride..	
Castor oil, polyoxyethylated (42 moles ethylene oxide)..	
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethylammonium chloride).	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Cationic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethyl-ammonium chloride).	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Chloral hydrate .....	Polymerization reaction-control agent.
<i>N</i> -Cyclohexyl- <i>p</i> -toluene sulfonamide..	
2,5-Di- <i>tert</i> -butyl hydroquinone.	

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List of substances	Limitations
<p>Diethanolamine..                      Diethylene glycol dibenzoate (CAS Reg. No. 120–55–8) .....                      Diethylene glycol monobutyl ether..                      Diethylene glycol monoethyl ether..                      Diethylenetriamine..                      N,N-Diisopropanolamide of tallow fatty acids..                      N-[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene..                      N,N-Dioleoyl-ethylenediamine, N,N-dilinoeoyl-ethylenediamine, and N-oleoyl-N-linoleoyl-ethylenediamine 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, and an acid value of 10 maximum. ASTM Method D127–60 "Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax" (Revised 1960) 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: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a>.</p>	<p>For use only as a plasticizer in polymeric substances.</p>
<p>Diphenylamine..                      Dipropylene glycol dibenzoate (CAS Reg. No. 27138–31–4) .....                      Disodium N-octadecylsulfosuccinamate..  <i>tert</i>-Dodecyl thioether of polyethylene glycol..                      Erucamide (erucylamide)..                      Ethanediol, polymer with tetrahydro-4-hydroxy-5-methyl-2(1<i>H</i>)pyrimidinone, propoxylated..                      Ethylene oxide .....                      Ethylene oxide adduct of mono-(2-ethylhexyl) o-phosphate..                      Fatty acid (C<sub>12</sub>-C<sub>18</sub>) diethanolamide..                      Fish oil fatty acids, hydrogenated, potassium salt..                      Formaldehyde..                      Glycerol monocaprate..                      Glycerol tribenzoate (CAS Reg. No. 614–33–5) .....                      Glyoxal..                      Glyoxal-urea-formaldehyde condensate (CAS Reg. No. 27013–01–0) formed by reaction in the molar ratio of approximately 47:33:15, respectively. The reaction product has a number average molecular weight of 278±14 as determined by a suitable method.                      Glyoxal-urea polymer (CAS Reg. No. 53037–34–6) .....                      Hexamethylenetetramine .....</p>	<p>For use only as plasticizer in polymeric substances.</p> <p>Fumigant in sizing.</p> <p>For use only as a plasticizer in polymeric coatings.</p> <p>For use as an insolubilizer for starch in coatings.</p> <p>For use as an insolubilizer for starch.</p> <p>Polymerization crosslinking agent for protein, including casein. As neutralizing agent with myristochromic chloride complex and stearato-chromic chloride complex.</p>
<p>Hexylene glycol (2-methyl-2,4-pentanediol)..                      Hydroabietyl alcohol..                      5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-hydroxypoly-[methylenoxy]methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane mixture.                      Imidazolium compounds, 2-(C<sub>17</sub> and C<sub>17</sub>-unsaturated alkyl)-1-[2-(C<sub>18</sub> and C<sub>18</sub>-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS Reg. No. 72749–55–4)..                      Isopropanolamine hydrochloride..                      Isopropyl <i>m</i>- and <i>p</i>-cresol (thymol derived)..                      Itaconic acid..                      Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt..                      Melamine-formaldehyde modified with:</p>	<p>For use only as an antibacterial preservative.</p> <p>For use only at levels not to exceed 0.5 percent by weight of the dry paper and paperboard.</p>
<p>Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl).                      Diethylenetriamine.                      Imino-bis-butylamine.                      Imino-bis-ethyleneimine.                      Imino-bis-propylamine.                      Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane.                      Sulfanilic acid.                      Tetraethylenepentamine.                      Triethylenetetramine.                      Methyl alcohol..                      Methyl ethers of mono-, di-, and tripropylene glycol..</p>	<p>Basic polymer.</p>

List of substances	Limitations
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt..	
Methylated poly( <i>N</i> -1,2-dihydroxyethylene-1,3-imidazolidin-2-one).	For use only as an in solubilizer for starch.
Modified polyacrylamide resulting from an epichlorohydrin addition to a condensate of formaldehyde-dicyandiamide-diethylene triamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25 °C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method).	For use only as a dry strength and pigment retention aid agent employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of dry fibers.
Mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of C <sub>15</sub> -C <sub>21</sub> groups.	For use only as an emulsifier.
Monoglyceride citrate..	
Myristic chromic chloride complex..	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt..	
Nickel..	
β-Nitrostyrene .....	Basic polymer.
Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea (CAS Reg. No. 68412-14-6), and the acetate salts thereof (CAS Reg. No. 68784-21-4), which may be emulsified with ethoxylated tallow alkyl amines (CAS Reg. No. 61791-26-2).	For use prior to sheet forming at levels not to exceed 12 pounds per ton of paper.
α- <i>cis</i> -9-Octadecenyl- <i>omega</i> -hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles..	
α-( <i>p</i> -Nonylphenyl)- <i>omega</i> -hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles..	
Oleic acid reacted with <i>N</i> -alkyl-(C <sub>16</sub> -C <sub>18</sub> ) trimethylenediamine..	
Oxidized soy isolate having 50 to 70 percent of its cystine residues oxidized to cysteic acid.	For use as a binder adhesive component of coatings.
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in § 176.170(b)(2).	For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings.
Petroleum hydrocarbon resins (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks)..	
Petroleum hydrocarbons, light and odorless..	
o-Phthalic acid modified hydrolyzed soy protein isolate..	
Pine oil..	
Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) complying with the identity described in § 176.170(a)..	
Polyamide-epichloro hydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetriamine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11–15 percent and chlorine level of 20–23 percent on a dry basis..	
Polyamide-ethyleneimine-epichlorohydrin resin is prepared by reacting equimolar amounts of adipic acid and three amines (21 mole percent of 1,2-ethanediamine, 51 mole percent of <i>N</i> -(2-aminoethyl)-1,3-propanediamine, and 28 mole percent of <i>N</i> , <i>N</i> '-1,2-ethanediybis(1,3-propanediamine)) to form a basic polyamidoamine which is modified by reaction with ethyleneimine (5.5:1.0 ethyleneimine:polyamidoamine). The modified polyamidoamine is reacted with a crosslinking agent made by condensing approximately 34 ethylene glycol units with (chloromethyl)oxirane, followed by pH adjustment with formic acid or sulfuric acid to provide a finished product as a formate (CAS Reg. No. 114133-44-7) or a sulfate (CAS Reg. No. 167678-43-5), having a weight-average molecular weight of 1,300,000 and a number-average molecular weight of 16,000..	

List of substances	Limitations
<p>Polyamide-ethyleneimine-epichlorohydrin resin (CAS Reg. No. 115340-77-7), prepared by reacting equimolar amounts of adipic acid and <i>N</i>-(2-aminoethyl)-1,2-ethanediamine to form a basic polyamidoamine which is modified by reaction with ethyleneimine, and further reacted with formic acid and (chloromethyl)oxirane-<math>\alpha</math>-hydro-omega-hydroxypoly(oxy-1,2-ethanediy)l..</p> <p>Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter..</p> <p>Poly [2-(diethylamino) ethyl methacrylate] phosphate..</p> <p>Polyethylene glycol (200) dilaurate..</p> <p>Polyethylene glycol monoisotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413-26-6).</p> <p>Polymers: Homopolymers and copolymers of the following monomers:</p> <ul style="list-style-type: none"> <li>Acrylamide.</li> <li>Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters.</li> <li>Acrylonitrile.</li> <li>Butadiene.</li> <li>Crotonic acid.</li> <li>Cyclol acrylate.</li> <li>Decyl acrylate.</li> <li>Diallyl fumarate.</li> <li>Diallyl maleate.</li> <li>Diallyl phthalate.</li> <li>Dibutyl fumarate.</li> <li>Dibutyl itaconate.</li> <li>Dibutyl maleate.</li> <li>Di(2-ethylhexyl) maleate.</li> <li>Dioctyl fumarate.</li> <li>Dioctyl maleate.</li> <li>Divinylbenzene.</li> <li>Ethylene.</li> <li>2-Ethylhexyl acrylate.</li> <li>Fumaric acid.</li> <li>Glycidyl methacrylate.</li> <li>2-Hydroxyethyl acrylate.</li> <li><i>N</i>-(Hydroxymethyl) acrylamide.</li> <li>Isobutyl acrylate.</li> <li>Isobutylene.</li> <li>Isoprene.</li> <li>Itaconic acid.</li> <li>Maleic anhydride and its methyl or butyl esters.</li> <li>Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.</li> <li>Methylstyrene.</li> <li>Mono(2-ethylhexyl) maleate.</li> <li>Monoethyl maleate.</li> <li>5-Norbornene-2,3-dicarboxylic acid, mono-<i>n</i>-butyl ester.</li> <li>Styrene.</li> <li>Vinyl acetate.</li> <li>Vinyl butyrate.</li> <li>Vinyl chloride.</li> <li>Vinyl crotonate.</li> <li>Vinyl hexoate.</li> <li>Vinylidene chloride.</li> <li>Vinyl pelargonate.</li> <li>Vinyl propionate.</li> <li>Vinyl pyrrolidone.</li> <li>Vinyl stearate.</li> <li>Vinyl sulfonic acid.</li> </ul> <p>Polymer prepared from urea, ethanedial, formaldehyde, and propionaldehyde (CAS Reg. No. 106569-82-8).</p> <p>Polyoxyethylene (minimum 12 moles) ester of tall oil (30%-40% rosin acids)..</p> <p>Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,900)..</p> <p>Polyvinyl alcohol..</p> <p>Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20-0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of <math>K_2Ti_4O_9</math> and <math>K_2Ti_6O_{13}</math>..</p>	<p>For use only as a surfactant at levels not to exceed 3 percent in latex formulations used in pigment binders for paper and paperboard.</p> <p>Basic polymer.</p> <p>For use only as a starch and protein reactant in paper and paperboard coatings.</p>

List of substances	Limitations
<p>Sodium diisobutylphenoxy diethoxyethyl sulfonate..                      Sodium diisobutylphenoxy monoethoxy ethylsulfonate..                      Sodium <i>n</i>-dodecylpolyethoxy (50 moles) sulfate..                      Sodium isododecylphenoxy polyethoxy (40 moles) sulfate..                      Sodium <i>N</i>-methyl-<i>N</i>-oleyl taurate..                      Sodium methyl silicate..                      Sodium nitrite..                      Sodium polyacrylate..                      Sodium bis-tridecylsulfosuccinate..                      Sodium xylene sulfonate..                      Stearato chromic chloride complex..                      Styrene-allyl alcohol copolymers..                      Styrene-methacrylic acid copolymer, potassium salt..                      Tetraethylenepentamine .....</p> <p><math>\alpha</math>-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl]-<i>omega</i>-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles..</p> <p><math>\alpha</math>-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl or <i>p</i>-nonylphenyl]-<i>omega</i>-hydroxypoly (oxyethylene) where nonyl group is a propylene trimer isomer..</p> <p>Tetrasodium <i>N</i>-(1,2-dicarboxyethyl)-<i>N</i>-octadecyl sulfosuccinamate..</p> <p>Toluene..</p> <p>Triethanolamine..</p> <p>Triethylenetetramine .....</p> <p>Triethylenetetramine monoacetate, partially stearoylated..</p> <p>Urea-formaldehyde chemically modified with:                      Alcohol (methyl, ethyl, butyl, isobutyl, propyl, or isopropyl).                      Aminomethylsulfonic acid.                      Diaminobutane.                      Diaminopropane.                      Diethylenetriamine.  <i>N,N</i>-Dioleylethylenediamine.                      Diphenylamine.  <i>N,N</i>-Distearoylethylenediamine.                      Ethylenediamine.                      Guanidine.                      Imino-bis-butylamine.                      Imino-bis-ethylamine.                      Imino-bis-propylamine.  <i>N</i>-Oleoyl-<i>N</i>-stearoylethylenediamine.                      Polyamines made by reacting ethylenediamine or triethylenediamine with dichloroethane or dichloropropane.                      Tetraethylenepentamine.                      Triethylenetetramine.</p> <p>Xylene..                      Xylene sulfonic acid-formaldehyde condensate, sodium salt..                      Zinc stearate..</p>	<p>Polymerization cross-linking agent.</p> <p>Polymerization cross-linking agent.</p>

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting §176.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

**§ 176.200 Defoaming agents used in coatings.**

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.