

§ 178.3125

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

List of substances	Limitations
Alum (double sulfate of aluminum and ammonium, potassium, or sodium).	
4-Chloro-3-methylphenol(<i>p</i> -chlorome-tacresol)	For use as preservative only.
Chromium potassium sulfate (chrome alum)	For use only in glue used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paper board.
3,5-Dimethyl-1,3,5- <i>H</i> -tetrahydrothiadia-zine-2-thione	For use as preservative only.
Disodium cyanodithioimidocarbonate	Do.
Defoaming agents	As provided in § 176.210 of this chapter.
Ethanolamine.	
Ethylenediamine.	
Formaldehyde	For use as a preservative only.
Potassium <i>N</i> -methylthiocarbamate	Do.
Potassium pentachlorophenate	Do.
Rosins and rosin derivatives	As provided in § 178.3870.
Sodium chlorate.	
Sodium dodecylbenzenesulfonate.	
Sodium 2-mercaptobenzothiazole	For use as preservative only.
Sodium pentachlorophenate	Do.
Sodium <i>o</i> -phenylphenate	Do.
Zinc dimethylthiocarbamate	Do.
Zinc 2-mercaptobenzothiazole	Do.

(e) The conditions of use are as follows:

(1) The use of animal glue in any substance or article that is the subject of a regulation in this subpart conforms with any specifications or limitations prescribed by such regulation for the finished form of the substance or article.

(2) It is used as an adhesive or component of an adhesive in accordance with the provisions of § 175.105 of this chapter.

(3) It is used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paperboard.

(4) It is used as a protective colloid in resinous and polymeric emulsion coatings.

§ 178.3125 Anticorrosive agents.

The substances listed in this section may be used as anticorrosive agents in

List of substances	Limitations
<i>N</i> -Acyl sarcosines where the acyl group is lauroyl, oleoyl, or derived from the combined fatty acids of coconut oil.	For use only: 1. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of polyolefin film used for packaging meat, fresh fruits, and fresh vegetables. The average thickness of such polyolefin film shall not exceed 0.003 inch. 2. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of ethylene-vinyl acetate copolymer film complying with § 177.1350 of this chapter and used for packaging meat, fresh fruits, fresh vegetables, and dry food of Type VIII described in table 1 of § 176.170(c) of this chapter. The average thickness of such ethylene-vinyl acetate copolymer film shall not exceed 0.003 inch when used for packaging meat, fresh fruits, and fresh vegetables.

food-contact materials subject to the provisions of this section:

Substances	Limitations
Zinc hydroxy phosphite (CAS Reg. No. 55799-16-1).	For use only as a component of resinous and polymeric food-contact coatings intended for repeated use in contact with dry foods.

[50 FR 21835, May 29, 1985]

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

The substances listed in paragraph (b) of this section may be safely used as antistatic and/or antifogging agents in food-packaging materials, subject to the provisions of this section:

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

List of substances	Limitations
Alpha-(Carboxymethyl)-omega-(tetradecyloxy)polyoxyethylene)	For use only as an antistatic and/or antifogging agent at levels not to exceed 0.2 pct by weight in polyolefin film not exceeding 0.001 inch thickness.
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ -C ₁₈ with not less than 50 percent C ₁₄ -C ₁₆).	For use only: 1. As antistatic agents at levels not to exceed 0.1 percent by weight of polyolefin films that comply with § 177.1520 of this chapter: <i>Provided</i> , that the finished olefin polymers contact foods of Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, and under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter. 2. As antistatic agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with § 177.1640(c) of this chapter under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
Aluminum Borate ((9Al ₂ O ₃)-2(B ₂ O ₃), CAS Reg. No. 11121-16-7) produced by reaction between aluminum oxide and/or aluminum hydroxide with boric acid and/or metaboric acid at temperatures in excess of 1000 °C.	For use only: 1. At levels not to exceed 1 percent by weight of polypropylene films complying with § 177.1520(c) of this chapter, item 1.1, of polyethylene films complying with § 177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of § 176.170(c) of this chapter, under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch. 2. At levels not to exceed 2 percent by weight of polypropylene films complying with § 177.1520(c) of this chapter, item 1.1, of polyethylene films complying with § 177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of § 176.170(c) of this chapter under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch.
<i>N,N</i> -Bis(2-hydroxyethyl)alkyl(C ₁₂ -C ₁₈)amine	For use only as an antistatic agent at levels not to exceed 0.1 pct by weight of polyolefin food-contact films.
<i>N,N</i> -bis(2-hydroxyethyl)alkyl (C ₁₃ -C ₁₅) amine (CAS Reg. No. 70955-14-5).	For use only: 1. As an antistatic agent at levels not to exceed 0.2 percent by weight in molded or extruded high-density polyethylene (having a density ≥0.95 g/cm ³ and polypropylene containers that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under types I, VI-B, VII-B, and VIII, under the conditions of use E through G described in Table 2 of § 176.170(c) of this chapter, provided such foods have a pH above 5.0. 2. As an antistatic agent at levels not to exceed 0.1 percent by weight in molded or extruded polypropylene homopolymers and copolymers that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types II, III, IV, V, VII-A, and IX, under the conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

List of substances	Limitations
<p><i>N,N</i>-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups (C₁-C₁₈) are derived from tallow.</p>	<p>For use only:</p> <ol style="list-style-type: none"> 1. As an antistatic agent at levels not to exceed 0.15 pct by weight in molded or extruded polyethylene containers that contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, IV-B, VI-B, VII-B, and VIII, under the conditions of use E through G described in table 2 of § 176.170(c) of this chapter provided such foods have a pH above 5.0. 2. As an antistatic agent at levels not to exceed 0.10 mg. per square inch of food-contact surface in vinylidene chloride copolymer coatings complying with § 175.320, § 177.1200, or § 177.1630 of this chapter, provided that such coatings contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, IV, VII, VIII, and IX under the conditions of use E through G described in table 2 of § 176.170(c) of this chapter. The finished copolymers shall contain at least 70 weight pct of polymer units derived from vinylidene chloride; and shall contain not more than 5 weight pct of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.
<p><i>N,N</i>-Bis(2-hydroxyethyl)dodecanamide produced when diethanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free diethanolamine; and contains no more than 0.5 percent by weight of <i>N,N</i> bis(2-hydroxyethyl)piperazine, as determined by paper chromatography method.</p>	<p>For use only:</p> <ol style="list-style-type: none"> 1. As an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in table 1 of § 176.170(c) of this chapter. 2. As an antistatic agent at levels not to exceed 0.2 percent by weight in polypropylene films complying with § 177.1520 of this chapter, and used in contact with food of Types I, II, III, IV, V, VI-B, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, and under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. The average thickness of such polypropylene film shall not exceed 0.001 inches (30 micrometers).
<p><i>N,N</i>-Bis(2-hydroxyethyl) dodecanamide produced when diethanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free diethanolamine; and contains no more than 0.5 percent by weight of <i>N,N</i>-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method.</p>	<p>For use only as an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in table 1 of § 176.170(c) of this chapter.</p>
<p><i>N,N</i>-Bis(2-hydroxyethyl) octadecylamine, Chemical Abstracts Service Registry No. 10213-78-2, <i>N</i>-(2-hydroxyethyl)-<i>N</i>-octadecylglycine (monosodium salt), Chemical Abstracts Service Registry No. 66810-88-6, and <i>N,N</i>-Bis(2-hydroxyethyl)-<i>N</i>-(carboxymethyl) octadecanaminium hydroxide (inner salt), Chemical Abstracts Service Registry No. 24170-14-7, as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with sodium monochloroacetate and sodium hydroxide, such that the final product has: A nitrogen content of 3.3–3.8 percent; a melting point of 42°–50 °C; and a pH of 10.0–11.5 in a 1 percent by weight aqueous solution.</p>	<p>For use only as an antistatic agent at levels not to exceed 0.45 percent by weight in polypropylene films complying with § 177.1520 of this chapter, and used for packaging food of Types I, II, III, IV, V, VI-B, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, and under conditions of use B through H described in table 2 of § 176.170(c). The average thickness of such polypropylene film shall not exceed 0.002 inch.</p>
<p>α-<i>n</i>-Dodecanol-<i>omega</i>-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of <i>n</i>-dodecanol with an average of 9.5 moles of ethylene oxide to form a condensate having a hydroxyl content of 2.7 to 2.9 pct and having a cloud point of 80 °C to 92 °C in 1 pct by weight aqueous solution.</p>	<p>For use only as an antistatic agent at levels not to exceed 0.2 pct by weight in low-density polyethylene film having an average thickness not exceeding 0.005 inch.</p>
<p>Glycerol ester mixtures of ricinoleic acid, containing not more than 50 percent monoricinoleate, 45 pct diricinoleate, 10 pct triricinoleate, and 3.3 pct free glycerine.</p>	<p>As an antifogging agent at levels not exceeding 1.5 pct by weight of permitted plasticized vinyl chloride homo-and/or copolymers.</p>
<p><i>N</i>-Methacryloyloxyethyl-<i>N,N</i>-dimethylammonium-α-<i>N</i>-methyl carboxylate chloride sodium salt, octadecyl methacrylate, ethyl methacrylate, cyclohexyl methacrylate, <i>N</i>-vinyl-2-pyrrolidone copolymer (CAS Reg. No. 66822-60-4).</p>	<p>For use only as an antistatic agent at levels not to exceed 0.2 percent by weight of polyolefin films that contact foods under the conditions of use B through H described in table 2 of § 176.170(c) of this chapter. The average thickness of such polyolefin film shall not exceed 0.02 centimeter (0.008 inch).</p>

List of substances	Limitations
Octadecanoic acid 2-[2-hydroxyethyl] octadecylamino]ethyl ester (CAS Reg. No. 52497-24-2), (octadecylimino) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2), as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with octadecanoic acid, such that the final product has: a maximum acid value of 5 mg KOH/g and total amine value of 86±6 mg KOH/g as determined by a method entitled "Total Amine Value," which is incorporated by reference. Copies of the method 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/lbr_locations.html .	For use only as an antistatic agent at levels such that the product of film thickness in microns times the weight percent additive does not exceed 16, in polypropylene films complying with § 177.1520(c)1.1 of this chapter, and used for packaging food (except for food containing more than 8 percent alcohol) under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.

[42 FR 14609, Mar. 15, 1977, as amended at 45 FR 56797, Aug. 26, 1980; 45 FR 85727, Dec. 30, 1980; 46 FR 13688, Feb. 24, 1981; 47 FR 26824, June 22, 1982; 51 FR 28932, Aug. 13, 1986; 56 FR 41457, Aug. 21, 1991; 58 FR 57556, Oct. 26, 1993; 60 FR 54430, Oct. 24, 1995; 60 FR 18351, Apr. 11, 1995; 62 FR 31511, June 10, 1997; 63 FR 38748, July 20, 1998; 64 FR 62585, Nov. 17, 1999]

§ 178.3280 Castor oil, hydrogenated.

Hydrogenated castor oil may be safely used in the manufacture of articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) The additive is used as follows:

Use	Limitations
1. As a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles authorized for food-contact use.	For use only at levels not to exceed 4 pct by weight of vinyl chloride polymers.
2. As a component of cellophane	Complying with § 177.1200 of this chapter.
3. As a component of resinous and polymeric coatings	Complying with § 175.300 of this chapter.
4. As a component of paper and paperboard in contact with aqueous and fatty food.	Complying with § 176.170 of this chapter.
5. As a component of closures with sealing gaskets for food containers.	Complying with § 177.1210 of this chapter.
6. As a component of cross-linked polyester resins	Complying with § 177.2420 of this chapter.
7. As a component of olefin polymers complying with § 177.1520 of this chapter.	For use only at levels not to exceed 2 percent by weight of the polymer.

[42 FR 14609, Mar. 15, 1977, as amended at 55 FR 8914, Mar. 9, 1990]

§ 178.3290 Chromic chloride complexes.

Myristo chromic chloride complex and stearato chromic chloride complex may be safely used as release agents in the closure area of packaging containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

nor exceed 7 micrograms of chromium per square inch of closure area.

(b) The packaging container which has its closure area treated with the release agent shall have a capacity of not less than 120 grams of food per square inch of such treated closure area.

§ 178.3295 Clarifying agents for polymers.

(a) The quantity used shall not exceed that reasonably required to accomplish the intended technical effect

Clarifying agents may be safely used in polymers that are articles or components of articles intended for use in