

Substances	Limitations
Sodium 2,2'-methylenebis(4,6-di- <i>tert</i> -butylphenyl)phosphate (CAS Reg. No. 85209-91-2)..	<p>For use only:</p> <ol style="list-style-type: none"> 1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H, described in table 2 of § 176.170(c), or foods of all types, limited to conditions of use C through H described in table 2 of § 176.170(c). 2. As a clarifying agent at a level not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1. The finished polypropylene may be used in contact with foods of all types under conditions of use A through H described in table 2 of § 176.170(c) of this chapter. 3. As a clarifying agent in olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts foods only of types I, II, IV-B, VI-A, VI-B, and VII-B as identified in table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H described in table 2 of § 176.170(c) of this chapter, or foods of types III, IV-A, V, VI-C, and VII-A as identified in table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in table 2 of § 176.170(c) of this chapter.

[46 FR 59236, Dec. 4, 1981, as amended at 52 FR 30920, Aug. 18, 1987; 53 FR 30049, Aug. 10, 1988; 54 FR 12432, Mar. 27, 1989; 54 FR 14734, Apr. 12, 1989; 55 FR 52990, Dec. 26, 1990; 56 FR 1085, Jan. 11, 1991; 59 FR 13650, Mar. 23, 1994; 59 FR 25323, May 16, 1994; 61 FR 33847, July 1, 1996; 61 FR 51588, Oct. 3, 1996; 61 FR 65943, Dec. 16, 1996]

§ 178.3297 Colorants for polymers.

The substances listed in paragraph (e) of this section may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions and definitions set forth in this section:

(a) The term *colorant* means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term "colorant" includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reason-

ably required to accomplish the intended coloring effect.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Center for Food Safety and Applied Nutrition, (HFS-200) Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(d) Color additives and their lakes listed for direct use in foods, under the provisions of the color additive regulations in parts 73, 74, 81, and 82 of this chapter, may also be used as colorants for food-contact polymers.

(e) List of substances:

Substances	Limitations
Aluminum. Aluminum hydrate. Aluminum and potassium silicate (mica). Aluminum mono-, di-, and tristearate. Aluminum silicate (China clay).	
4-[[5-[[[4-(Aminocarbonyl) phenyl] amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-2-naphthalene-carboxamide (C.I. Pigment Red 187, CAS Reg. No. 59487–23–9).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact foods only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
N-[4-(Aminocarbonyl)phenyl]-4-[[1-[[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzamide (C. I. Pigment Yellow 181, CAS Reg. No. 74441–05–7).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
Barium sulfate. Bentonite.	
Bentonite, modified with 3-dimethyldioctadecylammonium ion. 1,4-Bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 116–75–6).	For use at levels not to exceed 0.0004 percent byweight of polyethylene phthalate polymers complying with § 177.1630 of this chapter.
3,6-Bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254, CAS Reg. No. 84632–65–5).	For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in table 2 of § 176.170(c) of this chapter.
4,4'-Bis(4-anilino-6-diethanolamine- α -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt.	For use only in the textile fibers specified in § 177.2800 of this chapter.
4,4'-Bis(4-anilino-6-methylethanolamine- α -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt.	Do.
Burnt umber. Calcium carbonate. Calcium silicate. Calcium sulfate.	
Carbon black (channel process, prepared by the impingement process from stripped natural gas).	
4-Chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, calcium salt (1:1); (C.I. Pigment Yellow 191, CAS Reg. No. 129423–54–7).	For use at levels not to exceed 1.0 percent by weight of the finished polymers. The finished articles are to contact food only under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter.
Chromium oxide green, Cr ₂ O ₃ (C.I. pigment green 17, C.I. No. 77288).	For use only:
Cobalt aluminate	1. In olefin polymers complying with § 177.1520 of this chapter. 2. In repeat-use rubber articles complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber articles.
Cobalt aluminate	For use only:
Copper chromite black spinel (C.I. Pigment Black 28, CAS Reg. No. 68186–91–4)..	1. In resinous and polymeric coatings complying with § 175.300 of this chapter. 2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter. 3. Xylene-formaldehyde resins condensed with 4-4'isopropylidenediphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter. 4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter. 5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter. 6. At levels not to exceed 5 percent by weight of all polymers except those listed under limitations 1 through 5 of this item. The finished articles are to contact food under conditions of use A through H described in table 2 of § 176.170(c) of this chapter.
D&C Red No. 7 and its lakes. Diatomaceous earth.	
4,4'-Diamino-[1,1'-bianthracene]-9,9',10,10'-tetrone (CAS Reg. No. 4051–63–2).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
5-[[[2,3-Dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl]azo]-2,4,6(1H, 3H, 5H)-pyrimidinetrione (CAS Reg. No. 72102–84–2).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.

Substances	Limitations
3,3'-[(2,5-Dimethyl-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediylo)azo]]bis[4-chloro- <i>N</i> -(5-chloro-2-methylphenyl)-benzamide] (CAS Reg. No. 5280-80-8).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
3,3'-[(2,5-Dimethyl-1,4-phenylene)bis[imino-carbonyl(2-hydroxy-3,1-naphthalenediylo)azo]] bis(4-methylbenzoic acid), bis(2-chloroethyl) ester (CAS Reg. No. 68259-05-2)..	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
2,2'-[1,2-Ethanediylo]bis(oxy-2,1-phenyleneazo)]bis[N-(2,3-dihydro-2-oxo-1 <i>H</i> -benzimidazol-5-yl)]-3-oxo-butanamide (C.I. Pigment Yellow 180, CAS Reg. No. 77804-81-0).	For use at levels not to exceed 1.0 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through G described in table 2 of § 176.170(c) of this chapter.
2,2'-(1,2-Ethenediylo)di-4,1-phenylene bis(benzoxazole) (CAS Reg. No. 1533-45-5).	For use as an optical brightener for all polymers at a level not to exceed 0.025 percent by weight of polymer. The finished polymer shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter, under categories I, II, IV-B, VI-A, VI-B, VII-B, and VIII at temperatures not to exceed 275 °F.
High-purity furnace black (CAS Reg. No. 1333-86-4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[<i>a</i>]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled "Determination of PAH Content of Carbon Black," dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC..	For use at levels not to exceed 2.5 percent by weight of the polymer.
Iron oxides. Kaolin-modified, produced by treating kaolin with a reaction product of isopropyl titanate and oleic acid in which 1 mole of isopropyl titanate is reacted with 1 to 2 moles of oleic acid. The reaction product will not exceed 8 percent of the modified kaolin. The oleic acid used shall meet the requirements specified in § 172.860 of this chapter.	For use only in olefin polymers complying with § 177.1520 of this chapter at levels not to exceed 40 percent by weight of olefin polymer.
Magnesium oxide.	
Magnesium silicate (talc).	
Mixed methylated 4,4'-bis(2-benzoxazolylo)stilbenes with the major portion consisting of 4-(2-benzoxazolylo)-4'-(5-methyl-2-benzoxazolylo)stilbene (CAS Registry No. 5242-49-9) and lesser portions consisting of 4,4'-bis(5-methyl-2-benzoxazolylo)stilbene (CAS Registry No. 2397-00-4) and 4,4'-bis(2-benzoxazolylo)stilbene (CAS Registry No. 1533-45-5).	For use as an optical brightener only at levels not to exceed 0.05 percent by weight of rigid and semirigid polyvinyl chloride and not to exceed 0.03 percent by weight in all other polymers. The finished food-contact articles shall be used only under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.
7-(2 <i>H</i> -Naphtho[1,2- <i>d</i>]triazol-2-yl)-3-phenylcoumarin (CAS Reg. No. 3333-62-8) having a melting point of 250 °C to 251 °C and a nitrogen content of 10.7 to 11.2 percent.	For use as an optical brightener only in: 1. Olefin polymers complying with § 177.1520 of this chapter only at levels such that the product of concentration of the optical brightener (expressed in parts per million by weight of the olefin polymer) multiplied by the thickness of the olefin polymer (expressed in thousandths of an inch and limited to no more than 0.400 inch) shall not exceed 500; provided that the level of the brightener shall not exceed 20 parts per million by weight of the olefin polymer, and further that the olefin polymers shall comply with specifications for items 1.1, 2.1, 3.1, 3.3, and 4 of § 177.1520(c) of this chapter. The polymer may be used under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use E, F, and G. 2. Polyethylene terephthalate specified in § 177.2800(d)(5)(i) of this chapter at a level not to exceed 0.035 percent by weight of the finished fibers.

Substances	Limitations
1,1'-(6-Phenyl-1,3,5-triazine-2,4-diyldiimino)bis-9,10-anthracenedione (CAS Reg. No. 4118–16–5).	For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV–A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use D, E, F, and G.
Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147–14–8). Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260). C.I. Pigment red 38 (C.I. No. 21120)	For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.
Quinacridone red (C.I. Pigment violet 19, C.I. No. 73900). Sienna (raw and burnt). Silica.	
2,3,4,5-Tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with <i>p</i> -phenylenediamine and sodium methoxide (CAS reg. No. 106276–80–6).	For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in table 2, of § 176.170(c) of this chapter.
4,5,6,7-Tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinoliny]-1H-isoindole-1,3(2H)-dione (C. I. Pigment Yellow 138, CAS Reg. No.30125–47–4)..	For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use C through H, as described in table 2 of § 176.170(c) of this chapter; provided further that the finished articles shall not be filled at temperatures exceeding 158 °F (70 °C).
2,2'-(2,5-Thiophenediyl)-bis(5- <i>tert</i> -butylbenzoxazole) (CAS Reg. No. 7128–64–5)..	For use as an optical brightener: 1. In all polymers at levels not to exceed 0.015 percent by weight of the polymer. The finished articles are to contact food only under conditions of use A through H described in table 2 of § 176.170(c) of this chapter. 2. In all polymers at levels not to exceed 0.05 percent by weight of the polymer. The finished articles shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter, under Categories I, II, IV–B, VI–A, VI–B, VI–C, VII–B, and VIII under conditions of use A through H described in table 2 of § 176.170(c) of this chapter. 3. In adhesives complying with § 175.105 of this chapter and in pressure-sensitive adhesives complying with § 175.125 of this chapter.
Titanium dioxide. Titanium dioxide-barium sulfate. Titanium dioxide-magnesium silicate.	
Ultramarines	As identified in § 73.2725 of this chapter.
Zinc carbonate	For use only: 1. In resinous and polymeric coatings complying with § 175.300 of this chapter. 2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter. 3. Xylene-formaldehyde resins condensed with 4-4'-isopropylidene diphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter. 4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter. 5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.
Zinc chromate	For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.
Zinc oxide	For use only: 1. In resinous and polymeric coatings complying with § 175.300 of this chapter. 2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter. 3. Xylene-formaldehyde resins condensed with 4-4'-isopropylidene-diphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter. 4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter. 5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.

Substances	Limitations
Zinc sulfide	For use at levels not to exceed 10 percent by weight.

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §178.3297, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§178.3300 Corrosion inhibitors used for steel or tinplate.

Corrosion inhibitors may be safely used for steel or tinplate intended for use in, or to be fabricated as, food containers or food-processing or handling equipment, subject to the provisions of this section.

(a) The corrosion inhibitors are prepared from substances identified in this section and used subject to the limitations prescribed.

(b) The following corrosion inhibitors or adjuvants are used in amounts not to exceed those reasonably required to accomplish the intended physical or technical effect:

(1) Corrosion inhibitors (active ingredients) used in packaging materials for the packaging of steel or tinplate or articles fabricated therefrom:

List of substances	Limitations
Dicyclohexylamine and its salts of fatty acids derived from animal or vegetable oil. Dicyclohexylamine nitrite. Morpholine and its salts of fatty acids derived from animal or vegetable oils.	

(2) Adjuvants employed in the application and use of corrosion inhibitors:

List of substances	Limitations
Propylene glycol.	

§178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as emulsifiers and/or surface-active agents in the manufacture of articles or 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 quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface-active agent in any substance or article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

List of substances	Limitations
α -Alkyl-, α -alkenyl-, and α -alkylaryl- <i>omega</i> -hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of α -(2,4,6-triisobutylphenyl)- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of α -(Z)-9-octadecenyl- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and α -alkyl(C ₁₆ -C ₁₈)- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles.	For use only at levels not to exceed 0.5 pct by weight of coatings complying with § 175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in § 178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.
<i>n</i> -Alkylbenzenesulfonic acid (alkyl group consisting of not less than 95 percent C ₁₀ to C ₁₆) and its ammonium, calcium, magnesium, potassium, and sodium salts.	For use only as emulsifiers and/or surface active agents as components of nonfood articles complying with §§ 175.300, 175.320, 175.365, 175.380, 176.170, 176.180, 177.1010, 177.1200, 177.1210, 177.1630, 177.2600, and 177.2800 of this chapter and § 178.3120.