

§ 178.3297

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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"> <li>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).</li> <li>2. As a clarifying agent at levels not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1(a) or 1.1(b) and of olefin polymers complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b) (where the copolymers contain not less than 85 weight percent of the polymer units derived from polypropylene.) The finished polymers shall be used in contact with foods only under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.</li> <li>3. 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, item 2.2, where the finished polymer contacts food 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.</li> </ol>

[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; 63 FR 56789, Oct. 23, 1998; 63 FR 68392, Dec. 11, 1998; 64 FR 26843, May 18, 1999; 65 FR 16316, Mar. 28, 2000]

§ 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 reasonably 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 Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200

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(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). 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). Anthra(2,1,9-def:(6,5,10-d'e'f))disoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29; CAS Reg. No. 81-33-4).	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. 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. For use at levels not to exceed 1% by weight of 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.
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). 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 at levels not to exceed 0.0004 percent by weight of polyethylene phthalate polymers complying with § 177.1630 of this chapter. 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- $\alpha$ -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt. 4,4'-Bis(4-anilino-6-methylethanolamine- $\alpha$ -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt. Burnt umber. Calcium carbonate. Calcium silicate. Calcium sulfate. Carbon black (channel process, prepared by the impingement process from stripped natural gas).	For use only in the textile fibers specified in § 177.2800 of this chapter. Do.
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). 4-Chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, diammonium salt (1:2); (C.I. Pigment Yellow 191:1, CAS Reg. No. 154946-66-4).	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. For use at levels not to exceed 0.5 percent by weight of polymers. 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.
Chrome antimony titanium buff rutile (C.I. Pigment Brown 24, CAS Reg. No. 68186-90-3).	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 as described in Table 2 of § 176.170(c) of this chapter.
Chromium oxide green, Cr <sub>2</sub> O <sub>3</sub> (C.I. Pigment Green 17, C.I. No. 77288).	For use only: 1. In polymers used in contact with food at a level not to exceed 5 percent by weight of the polymer, except as specified below. 2. In olefin polymers complying with § 177.1520 of this chapter. 3. 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.

Substances	Limitations
Cobalt aluminate .....	<p>For use only:</p> <ol style="list-style-type: none"> <li>1. In resinous and polymeric coatings complying with § 175.300 of this chapter.</li> <li>2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter.</li> <li>3. Xylene-formaldehyde resins condensed with 4-4'isopropylidenediphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter.</li> <li>4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter.</li> <li>5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.</li> <li>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.</li> </ol>
Copper chromite black spinel (C.I. Pigment Black 28, CAS Reg. No. 68186–91–4).	<p>For use at levels not to exceed 5 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H as described in table 2 of § 176.170(c) of this chapter.</p>
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).	<p>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.</p>
2,9-Dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202, CAS Reg. No. 3089–17–6).	<p>For use at levels not to exceed 1.0 percent by weight of polymers.</p>
4,5-Dichloro-2-((5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl)azo)benzenesulfonic acid, calcium salt(1:1) (C.I. Pigment Yellow 183, CAS Reg. No. 65212–77–3).	<p>For use only:</p> <ol style="list-style-type: none"> <li>1. At levels not to exceed 1 percent by weight of polypropylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 1.2, 1.3, 3.1a, 3.1b, 3.1c, 3.2a, 3.2b, 3.4, or 3.5. The finished articles are to contact food only under conditions of use E through G, as described in Table 2 of § 176.170(c) of this chapter.</li> <li>2. At levels not to exceed 1 percent by weight of high density polyethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.1c, 3.2a, 3.2b, 3.6 (density not less than 0.94 grams per cubic centimeter), or 5. The finished articles are to contact food only under conditions of use E through G, as described in Table 2 of § 176.170(c) of this chapter.</li> </ol>
5-[(2,3-Dihydro-6-methyl-2-oxo-1 <i>H</i> -benzimidazol-5-yl)azo]-2,4,6(1 <i>H</i> , 3 <i>H</i> , 5 <i>H</i> )-pyrimidinetrone (CAS Reg. No. 72102–84–2).	<p>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.</p>
2,9-Dimethylantra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10(2 <i>H</i> ,9 <i>H</i> )-tetrone (C.I. Pigment Red 179, CAS Reg. No. 5521–31–3).	<p>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 as described in Table 2 of § 176.170(c) of this chapter.</p>
3,3'-[(2,5-Dimethyl-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediy)azo]]bis[4-chloro- <i>N</i> -(5-chloro-2-methylphenyl)-benzamide] (CAS Reg. No. 5280–80–8).	<p>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.</p>
3,3'-[(2,5-Dimethyl-1,4-phenylene)bis[imino-carbonyl(2-hydroxy-3,1-naphthalenediy) azo]] bis(4-methylbenzoic acid), bis(2-chloroethyl) ester (CAS Reg. No. 68259–05–2).	<p>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.</p>
2,2'-[1,2-Ethanediy]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).	<p>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.</p>
2,2'-(1,2-Ethenediydi-4,1-phenylene) bis(benzoxazole) (CAS Reg. No. 1533–45–5).	<p>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.</p>

Substances	Limitations
<p>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[a]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 Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or 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 at levels not to exceed 2.5 percent by weight of the polymer.</p>
<p>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.</p>	<p>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.</p>
<p>Magnesium oxide. Magnesium silicate (talco). Manganese Violet (manganese ammonium pyrophosphate; CAS Reg. No. 10101-66-3).</p>	<p>For use at levels not to exceed 2 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H as described in table 2 of § 176.170(c) of this chapter.</p>
<p>Mixed methylated 4,4'-bis(2-benzoxazolyl)stilbenes with the major portion consisting of 4-(2-benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene (CAS Registry No. 5242-49-9) and lesser portions consisting of 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene (CAS Registry No. 2397-00-4) and 4,4'-bis(2-benzoxazolyl)stilbene (CAS Registry No. 1533-45-5).</p>	<p>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.</p>
<p>7-(2H-Naphtho[1,2-d]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.</p>	<p>For use as an optical brightener only in:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>
<p>Nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53, CAS Reg. No. 8007-18-9).</p>	<p>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 as described in Table 2 of § 176.170(c) of this chapter.</p>
<p>1,1'-(6-Phenyl-1,3,5-triazine-2,4-diyldiimino)bis-9,10-anthracenedione (CAS Reg. No. 4118-16-5).</p>	<p>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.</p>
<p>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).</p>	

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

[48 FR 46775, Oct. 14, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 178.3297, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).