

Food and Drug Administration, HHS

§ 178.3740

derived petroleum wax is permitted in subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in §172.888 of this chapter.

§ 178.3725 Pigment dispersants.

Subject to the provisions of this regulation, the substances listed in this section may be safely used as pigment dispersants in food-contact materials.

Substances	Limitations
Dimethylolpropionic acid (CAS Reg. No. 4767-03-7)	For use only at levels not to exceed 0.45 percent by weight of the pigment. The pigmented articles may contact all foods under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter.
Phosphorylated tall oil fatty acids (CAS Reg. No. 68604-99-9), prepared by the reaction of dimethyl hydrogen phosphite with tall oil fatty acids.	For use only at levels not to exceed 1.0 percent by weight of the pigment. The pigmented polymeric films may contact all food under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.
Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, compd. with 1,1',1''-nitritoltris [2-propanol] (1:1) (CAS Reg. No. 221281-21-6).	For use only at levels not to exceed 0.45 percent by weight of the pigment. The pigmented articles may contact all food under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter.
Siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-oxoundecyl (CAS Reg. No. 155419-59-3).	For use only at levels not to exceed 0.5 percent by weight of the pigment. The pigmented polymers may contact all foods under conditions of use C, D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Trimethylolethane (CAS Reg. No. 77-85-0)	For use only at levels not to exceed 0.45 percent by weight of inorganic pigment. The pigmented articles may contact all food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

[61 FR 43157, Aug. 21, 1996, as amended at 63 FR 35799, July 1, 1998; 64 FR 48292, Sept. 3, 1999; 64 FR 72273, Dec. 27, 1999; 65 FR 52909, Aug. 31, 2000]

§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§561.310 and 561.340 of this chapter, or that are intended for use in contact with dried food in compliance with §§193.60 and 193.390 of this chapter.

graph (b) of this section may be safely used as plasticizers in polymeric substances used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in para-

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

(b) List of substances:

Substances	Limitations
Butylbenzyl phthalate	<p>For use only:</p> <ol style="list-style-type: none"> As provided in §§ 175.105 and 176.180 of this chapter. In polymeric substances used in food-contact articles complying with § 175.300, § 175.320, or § 176.170 of this chapter: <i>Provided</i>, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate. In polymeric substances used in other permitted food-contact articles: <i>Provided</i>, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and <i>Provided further</i>, That the finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 mg. per square inch, as determined by the methods prescribed in § 175.300(e) of this chapter.
1,3-Butylene glycoladipic acid polyester (1,700–2,200 molecular weight) terminated with a 16 percent by weight mixture of myristic, palmitic, and stearic acids.	<p>For use at levels not exceeding 33 percent by weight of polyvinyl chloride homopolymers used in contact with food (except foods that contain more than 8 percent of alcohol) at temperatures not to exceed room temperature. The average thickness of such homopolymers in the form in which they contact food shall not exceed 0.004 inch.</p>
Di(C ₇ , C ₉ -alkyl) adipate, in which the C ₇ , C ₉ -alkyl groups are derived from linear alpha olefins by the oxo process.	<p>For use only under the conditions listed below, and excluding use as a component of resinous and polymeric coatings described in § 175.300 of this chapter.</p> <ol style="list-style-type: none"> At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. At levels not to exceed 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Di- <i>n</i> -alkyl adipate made from C ₆ , C ₈ -C ₁₀ (predominately C ₈ and C ₁₀) or C ₈ -C ₁₀ synthetic fatty alcohols complying with § 172.864 of this chapter.	<p>For use only:</p> <ol style="list-style-type: none"> At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in which they contact food shall not exceed 0.002 inch.
Dicyclohexyl phthalate	<p>For use only:</p> <ol style="list-style-type: none"> As provided in §§ 175.105, 176.170, 176.180, and 177.1200 of this chapter. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.

Substances	Limitations
Di(2-ethylhexyl) adipate Diisononyl adipate	<p>For use only:</p> <ol style="list-style-type: none"> 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, non-alcoholic foods having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, non-alcoholic foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Diisononyl phthalate	<p>For use only at levels not exceeding 43 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, IV-B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</p>
Di(2-ethylhexyl) azelate	<p>For use only:</p> <ol style="list-style-type: none"> 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty, non-alcoholic food having a fat and oil content not exceeding a total of 30 percent by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Di- <i>n</i> -hexylazelate	<p>For use only:</p> <ol style="list-style-type: none"> 1. In polymeric substances used in contact with nonfatty food. 2. In polymeric substances used in contact with fatty food and limited to use at levels not exceeding 15 pct by weight of such polymeric substance except as provided under limitation 3. 3. At levels greater than 15 but not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F or G described in table 2 of § 176.170(c) of this chapter, with fatty food having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Dihexyl phthalate	<p>For use only:</p> <ol style="list-style-type: none"> 1. As provided in § 175.105 of this chapter. 2. In articles that contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, IV-B, VI-B, and VIII.
Diphenyl phthalate	<p>For use only:</p> <ol style="list-style-type: none"> 1. As provided in § 175.105 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
Epoxidized butyl esters of linseed oil fatty acids	Iodine number, maximum 5; oxirane oxygen, minimum 7.8 pct.
Epoxidized linseed oil	Iodine number, maximum 5; oxirane oxygen, minimum 9-pct.
Mineral oil, white.	

Substances	Limitations
Polybutene, hydrogenated (minimum viscosity at 99 °F, 39 Saybolt Universal seconds, as determined by ASTM methods D445-82 ("Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity)") and D2161-82 ("Standard Method for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity"), and bromine number of 3 or less, as determined by ASTM method D1492-78 ("Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration"), which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined 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 .	For use only: 1. In polymeric substances used in contact with non-fatty food. 2. In polyethylene complying with § 177.1520 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking. 3. In polystyrene complying with § 177.1640 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 5 pct by weight of the polystyrene, and further provided that such plasticized polystyrene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene (mol weight 300-5,000)	For use in polyethylene complying with § 177.1520 of this chapter, provided that the polyisobutylene is added in an amount not exceeding 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene complying with § 177.1420 of this chapter.	
Polypropylene glycol (CAS registry No. 25322-69-4) (minimum mean molecular weight 1,200).	For use only in polystyrene plastics, identified in § 177.1640(a)(1), in an amount not to exceed 6 pct by weight of the finished food-contact article.
Propylene glycol azelate (average mol. weight 3,000).	For use only at levels not exceeding 41 pct by weight of permitted polyvinyl chloride coatings. Such coatings shall be used only as bulk food contact surfaces of articles intended for repeated use, complying with § 177.2600 of this chapter.
Triethylene glycol 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	Diethylene glycol content not to exceed 0.1 pct. For use only in cellulosic plastics in an amount not to exceed 15 pct by weight of the finished food-contact article, provided that the finished plastic article contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, VI-B, VII-B, and VIII.

(c) The use of the plasticizers in any polymeric substance or article subject to any regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

[42 FR 14609, Mar. 15, 1977, as amended at 42 FR 44223, Sept. 2, 1977; 45 FR 56052, Aug. 22, 1980; 48 FR 5748, Feb. 15, 1984; 49 FR 10113, Mar. 19, 1984; 51 FR 47011, Dec. 30, 1986]

§ 178.3750 Polyethylene glycol (mean molecular weight 200-9,500).

Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in § 172.820(b) of this chapter.

(c) The provisions of paragraph (b) of this section are not applicable to polyethylene glycols used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 178.3760 Polyethylene glycol (400) monolaurate.

Polyethylene glycol (400) monolaurate containing not more than 0.1 percent by weight of ethylene and/or diethylene glycol may be used at a level not to exceed 0.3 percent by weight of twine as a finish on twine to