

Food and Drug Administration, HHS

§ 178.3725

States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in §172.886(b) of this chapter:

Ultraviolet absorbance per centimeter pathlength:

Millimicrons	Maximum
280 to 289	0.25
290 to 29920
300 to 35914
360 to 40004

(c) It is used or intended for use as a protective coating of the surfaces of metal or wood tanks used in fermentation process, in an amount not in excess of that required to produce its intended effect.

(d) Petrolatum as defined by this section may be used for the functions described and within the limitations prescribed by specific regulations in parts 175, 176, 177, and 178 of this chapter which prescribe uses of petrolatum. For the purpose of cross-reference, such specific regulations include: §§175.105, 175.125, 175.300, 176.170, 176.200, 176.210, 177.2600, 177.2800, and 178.3570 of this chapter.

(e) Petrolatum may contain any antioxidant permitted in food by regulations issued pursuant to section 409 of the act, in an amount not greater than that required to produce its intended effect.

[42 FR 14609, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984; 55 FR 12172, Apr. 2, 1990]

§ 178.3710 Petroleum wax.

Petroleum wax may be safely used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed in this section.

(b) The petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in §172.886(b) of this chapter.

Ultraviolet absorbance per centimeter pathlength:

Millimicrons	Maximum
280 to 289	0.15
290 to 29912
300 to 35908
360 to 40002

(c) Petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(d) Petroleum wax may contain a total of not more than 1 weight percent of residues of the following polymers when such residues result from use of the polymers as processing aids (filter aids) in the production of the petroleum wax: Homopolymers and/or copolymers derived from one or more of the mixed *n*-alkyl (C₁₂, C₁₄, C₁₆, and C₁₈) methacrylate esters where the C₁₂ and C₁₄ alkyl groups are derived from coconut oil and the C₁₆ and C₁₈ groups are derived from tallow.

(e) Petroleum wax may contain 2-hydroxy-4-*n*-octoxybenzophenone as a stabilizer at a level not to exceed 0.01 weight percent of the petroleum wax.

(f) Petroleum wax may contain poly(alkylacrylate) (CAS Reg. No. 27029-57-8), as described in §172.886(c)(2) of this chapter, as a processing aid in the manufacture of petroleum wax.

[42 FR 14609, Mar. 15, 1977, as amended at 51 FR 19545, May 30, 1986]

§ 178.3720 Petroleum wax, synthetic.

Synthetic petroleum wax may be safely used in applications and under the same conditions where naturally 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.

§ 178.3730

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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''-nitrilotris [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.

§ 178.3740 Plasticizers in polymeric substances.

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

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.

(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	For use only: 1. As provided in §§ 175.105 and 176.180 of this chapter. 2. 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. 3. 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.	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.