

**§ 178.3690**

**21 CFR Ch. I (4–1–13 Edition)**

**§ 178.3690 Pentaerythritol adipate-stearate.**

Pentaerythritol adipate-stearate identified in paragraph (a) of this section may be safely used as a lubricant in the fabrication of rigid and semi-rigid polyvinyl chloride and/or vinyl chloride-propylene copolymers complying with §177.1980 of this chapter used as articles or components of articles that contact food, excluding food with alcohol content greater than 8 percent under conditions of use of E, F, and G described in table 2 in §175.300(d) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, pentaerythritol adipate-stearate is an ester of pentaerythritol with adipic acid and stearic acid and its associated fatty acids (chiefly palmitic), with adipic acid comprising 14 percent and stearic acid and its associated acids (chiefly palmitic) comprising 71 percent of the organic moieties.

(b) *Specifications.* Pentaerythritol adipate-stearate has the following specifications:

(1) Melting point (dropping) of 55–58 °C as determined by ASTM method D566–76 (Reapproved 1982), “Standard Test Method for Dropping Point of Lubricating Grease,” which is 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(2) Acid value not to exceed 15 as determined by ASTM method D1386–78, “Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes” (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(3) Saponification number of 270–280 as determined by ASTM method D1387–78, “Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes” (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(4) Iodine number not to exceed 2 as determined by Iodine Absorption Number, Hanus Method, of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” sections 28.018–28.019, 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The total amount of ester (calculated as free pentaerythritol) shall not exceed 0.4 percent by weight of the polyvinyl chloride and/or the vinyl chloride-propylene copolymers complying with §177.1980.

[45 FR 1018, Jan. 4, 1980, as amended at 47 FR 11848, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984; 54 FR 24898, June 12, 1989; 57 FR 18082, Apr. 29, 1992; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

**§ 178.3700 Petrolatum.**

Petrolatum may be safety used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petrolatum complies with the specifications set forth in the United

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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 299 .....	.20
300 to 359 .....	.14
360 to 400 .....	.04

(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 299 .....	.12
300 to 359 .....	.08
360 to 400 .....	.02

(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 (C<sub>12</sub>, C<sub>14</sub>, C<sub>16</sub>, and C<sub>18</sub>) methacrylate esters where the C<sub>12</sub> and C<sub>14</sub> alkyl groups are derived from coconut oil and the C<sub>16</sub> and C<sub>18</sub> 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.