

§ 178.3650

21 CFR Ch. I (4-1-07 Edition)

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 mμ. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (mμ), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 mμ, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m) by the base-line technique described in ASTM method E169-63 (Re-approved 1981), "Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

$$\text{Absorbance due to pyrene} = \frac{C_p \times S_a}{S_p}$$

where:

C<sub>p</sub>=Calculated concentration of pyrene in sample solution;

S<sub>p</sub>=Concentration of pyrene reference standard solution in same units of concentration;

S<sub>a</sub>=Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

$$\text{Pyrene content (p. p. m.)} = \frac{(200/1000) \times C}{20/1000} = 10C$$

where:

C=Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum

absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 mμ, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

- (1) Odor is faint and not kerosenic.
- (2) Initial boiling point is 300 °F minimum.
- (3) Final boiling point is 650 °F maximum.
- (4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

Wavelength (Mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289 .....	4.0
290 to 299 .....	3.3
300 to 329 .....	2.3
330 to 360 .....	.8

(c) The additive is used as follows:

Use	Limitations
As a plasticizer and absorber oil in the manufacture of polyolefin articles authorized for food contact use.	In an amount not to exceed that required to produce intended effect, consistent with good manufacturing practice.
As a lubricant of fibers of textiles authorized for food contact use.	At a use level not to exceed 0.15 percent by weight of finished fibers.
As a component of adhesives .....	Complying with § 175.105 of this chapter.
As a defoamer in the manufacture of paper and paperboard ....	Complying with § 176.210 of this chapter.

Use	Limitations
As a defoamer in coatings .....	Complying with § 176.200 of this chapter.

**§ 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