

(4) Ultraviolet absorbance limits specified in paragraph (a)(4) of this section, as determined by the analytical method described therein.

(c) The polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids, identified in paragraph (a) or (b) of this section, may also be used as a component of an aqueous dispersion of vinylidene chloride copolymers, subject to the conditions described in paragraphs (c) (1) and (2) of this section.

(1) The aqueous dispersion of the additive contains not more than 18 percent polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids, not more than 2 percent poly(oxyethylene) (minimum 20 moles of ethylene oxide) oleyl ether (CAS Reg. No. 9004-98-2), and not more than 1 percent poly(oxyethylene) (minimum 3 moles ethylene oxide) cetyl alcohols (CAS Reg. No. 9004-95-9).

(2) The aqueous dispersion described in paragraph (c)(1) of this section is used as an additive to aqueous dispersions of vinylidene chloride copolymers, regulated in §§175.300, 175.320, 175.360, 176.170, 176.180, and 177.1630 of this chapter, at levels not to exceed 1.5 percent (solids basis) in the finished coating.

(d) The polyhydric alcohol esters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food contact articles prepared from vinyl chloride polymers. Such esters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthofen process) montan wax acids with glycerol followed by neutralization:

(1) Dropping point 79 to 85 °C, as determined by the American Society for Testing and Materials (ASTM), Method D-566-76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(2) Acid value 20-30, as determined by ASTM Method D-1386-78 "Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978) (which is incorporated by

reference in accordance with 5 U.S.C. 552(a); the availability of this incorporation by reference is given in paragraph (a)(2) of this section), using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.

(3) Saponification value 130-160, as determined by ASTM Method D-1387-78 "Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), (which is incorporated by reference in accordance with 5 U.S.C. 552(a); the availability of this incorporation by reference is given in paragraph (a)(3) of this section), using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in the preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits specified in paragraph (a)(4) of this section, as determined by the analytical method described therein.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11848, Mar. 19, 1982; 49 FR 10113, Mar. 19, 1984; 51 FR 33895, Sept. 24, 1986; 54 FR 24898, June 12, 1989; 55 FR 28020, July 9, 1990; 58 FR 17512, Apr. 5, 1993; 69 FR 24512, May 4, 2004]

§ 178.3780 Polyhydric alcohol esters of long chain monobasic acids.

Polyhydric alcohol esters of long chain monobasic acids identified in this section may be safely used as lubricants in the fabrication of polyvinyl chloride and/or polyvinyl chloride copolymer articles complying with §177.1980 of this chapter that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII identified in table 1 in §176.170(c) of this chapter under conditions of use E, F, and G described in table 2 in §176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, polyhydric alcohol esters of long chain monobasic acids consist of polyhydric alcohol esters having number average molecular weights in the range of 1,050 to 1,700. The esters are produced by the reaction of either ethylene glycol or glycerol with long chain monobasic acids containing from 9 to 49 carbon atoms obtained by the ozonization of long chain *alpha*-olefins, the unreacted carboxylic acids in the formation of the glycerol esters being

neutralized with calcium hydroxide to produce a composition having up to 2 percent by weight calcium. The *alpha*-olefins, obtained from the polymerization of ethylene, have 20 to 50 carbon atoms and contain a minimum of 75 percent by weight straight chain *alpha*-olefins and not more than 25 percent vinylidene compounds.

(b) *Specifications*. The polyhydric alcohol esters have the following specifications:

(1) Melting point of 60–80 °C for the ethylene glycol ester and 90–105 °C for the glycerol ester as determined by the Fisher Johns method as described in “Semimicro Qualitative Organic Analysis—The Systematic Identification of Organic Compounds,” by Cheronis and Entrikin, 2d Ed., Interscience Publishers, NY, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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.

(2) Acid value 15–25 for each ester as determined by the A.O.C.S. method Trla-64T “Titer Test,” which is incorporated by reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, 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. The method is modified to use as the acid solvent a 1:1 volume mixture of anhydrous isopropyl alcohol and toluene. The solution is titrated with 0.1N methanolic sodium hydroxide.

(3) Saponification value 120–160 for the ethylene glycol ester and 90–130 for the glycerol ester as determined the A.O.C.S. method Trla-64T “Saponification Value,” which is incorporated by

reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, 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.

(4) Ultraviolet absorbance as specified in §178.3770(a)(4) of this chapter when tested by the analytical method described therein.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11849, Mar. 19, 1982; 54 FR 24899, June 12, 1989; 61 FR 14481, Apr. 2, 1996]

§ 178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in semirigid and rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers and/or from vinyl chloride copolymers complying with §177.1950, §177.1970, and/or §177.1980 of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polymer modifiers are identified as follows:

(1) Acrylic polymers identified in this subparagraph provided that such polymers contain at least 50 weight-percent of polymer units derived from one or more of the monomers listed in paragraph (a)(1)(i) of this section.

(i) Homopolymers and copolymers of the following monomers:

n-Butyl acrylate.
n-Butyl methacrylate.
 Ethyl acrylate.
 Methyl methacrylate.

(ii) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1)(i) of this section with one or more of the following monomers:

Acrylonitrile.
 Butadiene.
 α -Methylstyrene.
 Styrene.
 Vinylidene chloride.