

§ 178.3770 Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids.

Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) 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 polyvinyl chloride and/or from vinyl chloride copolymers complying with §177.1980 of this chapter. Such esters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthofen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

(1) Dropping point 76°-105 °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, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) Acid value 10-20, as determined by ASTM method D1386-78 ("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), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.

(3) Saponification value 100-160, as determined by ASTM method D1387-78 ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from Amer-

ican Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits as follows, as determined by the analytical method described in this subparagraph:

Ultraviolet absorbance per centimeter pathlength.

Millimicrons	Maximum
280 to 289	0.07
290 to 29906
300 to 35904
360 to 40001

ANALYTICAL METHOD

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 1,000-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable balljoint at the top.

Chromatographic tube. 1,200 millimeters in length, inside diameter to be 16.5 millimeters ±0.5 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of

the column with the female joint is 1,255 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately $\frac{3}{16}$ -inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jackets. Conical, for 500-milliliter and 1,000-milliliter separatory funnels. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. $2\frac{1}{4}$ joints, fitted with a drying tube, length optional.

Evaporation flasks (optional). A 250-milliliter or 500-milliliter capacity and a 1-liter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide) 2-liter distillation flask with heating mantle; Vigreux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Oil bath. Capable of heating to 90 °C.

Spectrophotometric cells. Fused quartz cells, optical pathlength in the range 1.000 centimeter ± 0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons-400 millimicrons with spectral slit width of 0.2 millimicron or less; under instrument operating conditions for these absorbance measurements. The spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ± 0.01 at 0.4 absorbance.

Absorbance accuracy,¹ ± 0.05 at 0.4 absorbance.

Wavelength repeatability, ± 0.2 millimicron.

¹As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

Wavelength accuracy, ± 1.0 millimicron.

Recording time, 50 seconds.

Time constant, 0.6 second.

Sensitivity, 30.

Ordinate scale, 90-100 percent transmission through scale.

Abscissa scale, 8X.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane and benzene designated in the list following this paragraph shall pass the following test:

To be specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters volume. Determine the absorbance in the 1-centimeter pathlength cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter pathlength between 280 μ and 400 μ .

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference point between 280 μ -400 μ . The absorbance per centimeter pathlength

shall not exceed 0.00 in this range. If necessary, purify by filtering through a column containing 100 grams of aluminum oxide (use same grade as described below) in the lower half and 100 grams of activated silica gel in the upper half keeping the column at 150 °C., for a period of 15 hours or overnight. The first 100 milliliters of eluate are used. Purification can also be accomplished by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 18° minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5-10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under "Reagents and materials" for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance in 1-centimeter pathlength cells compared to isooctane as reference. The absorbance of the solution should not exceed 0.02 per centimeter pathlength in the 280 m μ -400 m μ range. (NOTE: Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50

grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-liter distillation flask of the vacuum distillation assembly and distill at approximately 3-millimeter Hg pressure or less. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Aluminum oxide (80-200 mesh Woelm neutral activity grade 1 [Brockmann], Alupharm Chemicals, New Orleans, La., or equivalent). Pipette 1 milliliter of distilled water into a dry 250-milliliter Erlenmeyer flask equipped with a ground-glass stopper. Stopper the flask and rotate it in such a manner as to completely wet out the inside surfaces. When this has been done add 180 grams of the aluminum oxide and shake until no lumps or wet spots remain. Allow to stand at room temperature for a period of 2 hours. At the end of this time the water should be evenly distributed throughout the aluminum oxide powder, and it should have the same free flowing properties as the original material (flow velocity with water 0.2 milliliter per minute). At this point the aluminum oxide has an activity of 1 as expressed in Brockmann degrees, and the amount of added water is 0.5 percent by volume. This product is used in toto and as is, without further screening.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter pathlength between 280 m μ and 400 m μ when tested as prescribed under

“Organic solvents.” Usually three portions of wash solvent are sufficient.

PROCEDURE

Before proceeding with analysis of a sample, determine the absorbance in a 1-centimeter path cell between 250 m μ and 400 m μ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectrum after the complete procedure as prescribed. The absorbance per centimeter pathlength following the complete procedure should not exceed 0.04 in the wavelength range from 280 m μ to 299 m μ , inclusive, nor 0.02 in the wavelength range from 300 m μ to 400 m μ . If in either spectrum the characteristic benzene peaks in the 250 m μ -260 m μ region are present, remove the benzene by the procedure under “Organic solvents” and record absorbance again. Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

In a 1-liter separatory funnel place a representative 25-gram sample of wax, add 50 milliliters of isooctane, heat gently, stir until the wax is in solution; add 100 milliliters of preequilibrated sulfoxide-phosphoric acid mixture and shake, making sure it remains in solution. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under “Reagents and Materials” for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane using an aspirator vacuum under nitrogen and in an oil bath temperature of approximately 90 °C. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, re-evaporate to 1 milliliter of hexadecane, and repeat this operation once.

Reserve the residue for column chromatography on the aluminum oxide. Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 180 grams of the aluminum oxide and pour the adsorbent mixture into the chromatographic tube in approximately 30-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 180 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 80 centimeters in depth. Turn off the vacuum and remove the suction flask. Dissolve the hexadecane residue in 10 milliliters of warm benzene and decant the solution onto the column and allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 10-

milliliter portions of benzene swirling the flask repeatedly each time to assure adequate washing of the residue. Fix the 1,000-milliliter reservoir onto the top of the chromatographic column. Just before the final 10-milliliter wash reaches the top of the adsorbent, add 670 milliliters of benzene to the reservoir and continue the percolation at the 2-3 milliliter per minute rate until a total of 670 milliliters of benzene has been utilized. Collect the eluate in a clean 1-liter Erlenmeyer flask (or optionally into a 1-liter evaporation flask). Allow the column to drain until most of the solvent mixture is removed. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic Solvents." Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 m μ -400 m μ . Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 m μ -260 m μ region, evaporate the solution to remove benzene by the procedure under "Organic Solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in paragraph (a) of this section, the wax meets the ultraviolet absorbance specifications.

(b) The polyhydric alcohol esters identified in this paragraph may be used as release agents in resinous and polymeric coatings for polyolefin films complying with § 175.320 of this chapter. Such esters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthofen process) montan wax acids with equimolar proportions of ethylene glycol and 1,3-butanediol:

(1) Dropping point 77°-82 °C, as determined by ASTM method D566-76 (Re-approved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(2) Acid value 25-35, as determined by ASTM method D1386-78 ("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), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 1:2 ratio.

(3) Saponification value 135-150, as determined by ASTM method D1387-78 ("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), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in 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.

(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. 9005-98-2), 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]

§ 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, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal