

§ 177.1315

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

not to exceed 0.5 milligram per square inch of food-contact surface when tested by methods described in §176.170(d) of this chapter.

(4) The provisions of this section are not applicable to ethylene-carbon monoxide copolymers complying with §175.105 of this chapter.

[57 FR 32422, July 22, 1992]

§ 177.1315 Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.

Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymer may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and of part 174 of this chapter.

(a) *Identity.* For the purposes of this section, ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers (1,4-benzene dicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25640-14-6) or (1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25038-91-9) are basic copolymers meeting the specifications prescribed in paragraph (b) of this section, to which may have been added certain optional substances required in their production or added to impart desired physical or technical properties.

(b) *Specifications:*

| Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers | Inherent viscosity | Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface) | Test for orientability | Conditions of use |
|---|---|--|---|--|
| 1. <i>Non-oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 66 mole percent of ethylene glycol and 1 to 34 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer). | Inherent viscosity of a 0.50 percent solution of the copolymer in phenol-tetrachloroethane (60:40 ratio wt/wt) solvent is not less than 0.669 as determined by using a Wagner viscometer (or equivalent) and calculated from the following equation: Inherent viscosity = (Natural logarithm of N_1/c) where: N_1 =Ratio of flow time of the polymer solution to that of the solvent, and c =concentration of the test solution expressed in grams per 100 milliliters.do | (1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with water added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article. (2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with 3 percent (by volume) aqueous acetic acid added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article. | No test requireddo | In contact with foods, including foods containing not more than 25 percent (by volume) aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C (180 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container. Do. |

| Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers | Inherent viscosity | Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface) | Test for orientability | Conditions of use |
|---|--------------------|--|--|---|
| |do | (3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5. |do | Do. |
| |do | (4) 0.16 microgram per square centimeter (1.0 microgram per square inch) of food-contact surface when extracted for 24 hours with 25 percent (by volume) aqueous ethanol at 48.9 °C (120 °F). |do | Do. |
| 2. <i>Oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 85 mole percent ethylene glycol and 1 to 15 mole percent of 1,4-cyclohexane-dimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer). |do | (1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of the oriented copolymer when extracted with water added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article. | When extracted with heptane at 65.6 °C (150 °F) for 2 hours: terephthaloyl moieties do not exceed 0.09 microgram per square centimeter (0.60 microgram per square inch) of food-contact surface. | In contact with non-alcoholic foods including carbonated beverages. Conditions of hot fill not exceeding 87.8 °C (190 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container. |
| |do | (2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 3 percent (by volume) aqueous acetic acid added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article. |do | Do. |
| |do | (3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface of oriented copolymer when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5. |do | Do. |
| |do | (4) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 20 percent (by volume) aqueous ethanol heated to 65.6 °C (150 °F) for 20 minutes and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article. |do | In contact with foods and beverages containing up to 20 percent (by volume) alcohol. Conditions of thermal treatment in the container not exceeding 65.6 °C (150 °F) for 20 minutes. Storage at temperatures not in excess of 48.9 °C (120 °F). |

| Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers | Inherent viscosity | Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface) | Test for orientability | Conditions of use |
|--|----------------------|---|------------------------|---|
| 3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer). | No test required ... | (5) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 50 percent (by volume) aqueous ethanol at 48.9 °C (120 °F) for 24 hours. For each corresponding condition of use, must meet specifications described in § 177.1630(f), (g), (h), or (j). | No test required ... | In contact with foods and beverages containing up to 50 percent (by volume) alcohol. Conditions of fill and storage not exceeding 48.9 °C (120 °F). No thermal treatment in the container. For each corresponding specification, may be used as a base sheet and base polymer in accordance with conditions of use described in § 177.1630(f), (g), (h), or (j). |

(c) *Analytical method for determination of extractability.* The total extracted terephthaloyl moieties can be determined in the extracts, without evaporation of the solvent, by measuring the ultraviolet (UV) absorbance at 240 nanometers. The spectrophotometer (Varian 635-D, or equivalent) is zeroed with a sample of the solvent taken from the same lot used in the extraction tests. The concentration of the total terephthaloyl moieties in water, 3 percent acetic acid, and in 8 percent aqueous alcohol is calculated as bis(2-hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cyclic trimer (C₆H₄CO₂C₂H₄CO₂)₃, by reference to standards prepared in 95:5 percent (v/v) heptane:tetrahydrofuran.

[45 FR 39252, June 10, 1980, as amended at 47 FR 24288, June 4, 1982; 49 FR 25629, June 22, 1984; 51 FR 22929, June 24, 1986; 60 FR 57926, Nov. 24, 1995]

§ 177.1320 Ethylene-ethyl acrylate copolymers.

Ethylene-ethyl acrylate copolymers may be safely used to produce packaging materials, containers, and equipment intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Ethylene-ethyl acrylate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and ethyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, prior sanction, or approvals.

(b) The ethyl acrylate content of the copolymer does not exceed 8 percent by