### §177.1320

## 21 CFR Ch. I (4-1-01 Edition)

Ethylene-1,4- cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the fin- ished form at specified tem- peratures and times (ex- pressed in micrograms of the terephthaloyl moletles/square centimeter of food-contact sur- face)	Test for orientability	Conditions of use
3. Ethylene-1,4- cyclohexylene dimethylene terephthalate copoly- mer is the reaction product of dimethyl terephthalate or ter- ephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4- cyclohexanedimethan- ol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).	No test required	For each corresponding condi- tion of use, must meet speci- fications described in § 177.1630(f), (g), (h), or (j).	No test required	For each corresponding specification, may be used as a base sheet and base polymer in accordance with con- ditions of use de- scribed 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(2hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cvclic trimer  $(C_6H_4CO_2C_2H_4CO_2)_{3}$ 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 weight unless it is blended with polyethylene or with one or more olefin copolymers complying with \$177.1520 or with a mixture of polyethylene and one or more olefin copolymers, in such proportions that the ethyl acrylate content of the blend does not exceed 8 percent by weight, or unless it is used in a coating complying with \$175.300 or \$176.170 of this chapter, in such proportions that the ethyl acrylate content does not exceed 8 percent by weight of the finished coating.

(c) Ethylene-ethyl acrylate copolymers or the blend shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the

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ethyl acrylate content limits prescribed in paragraph (b) of this section, and the extractability limits prescribed in paragraph (c)(2) of this section, when tested by the methods prescribed for polyethylene in \$177.1520.

(1) Specifications—(i) Infrared identification. Ethylene-ethyl acrylate copolymers can be identified by their characteristic infrared spectra.

(ii) Quantitative determination of ethyl acrylate content. The ethyl acrylate can be determined by the infrared spectra. Prepare a scan from 10.5 microns to 12.5 microns. Obtain a baseline absorbance at 11.6 microns and divide by the plaque thickness to obtain absorbance per mil. From a previously prepared calibration curve, obtain the amount of ethyl acrylate present.

(iii) Specific gravity. Ethylene-ethyl acrylate copolymers have a specific gravity of not less than 0.920 nor more than 0.935, as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," 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) *Limitations*. Ethylene-ethyl acrylate copolymers or the blend may be used in contact with food except as a component of articles used for packaging or holding food during cooking provided they meet the following extractability limits:

(i) Maximum soluble fraction of 11.3 percent in xylene after refluxing and subsequent cooling to 25  $^{\circ}\mathrm{C}.$ 

(ii) Maximum extractable fraction of 5.5 percent when extracted with *n*-hexane at 50  $^{\circ}$ C.

(d) The provisions of paragraphs (b) and (c)(2) of this section are not applicable to ethylene-ethyl acrylate copolymers used in the formulation of adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10108, Mar. 19, 1984]

## §177.1330 Ionomeric resins.

Ionomeric resins manufactured from either ethylene-methacrylic acid copolymers (and/or their ammonium. calcium, magnesium, potassium, sodium, and/or zinc partial salts), ethylenemethacrylic acid-vinyl acetate copolymers (and/or their ammonium, calcium, magnesium, potassium, sodium, and/or zinc partial salts,), or methacrylic acid polymers with ethylene and isobutyl acrylate (and/or their potassium, sodium and/or zinc partial salts) may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methacrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and methacrylic acid such that the copolymers contain no more than 20 weight percent of polymer units derived from methacrylic acid, and the ethylene-methacrylic acidvinyl acetate copolymers consist of basic copolymers produced by the copolymerization of ethylene, methacrylic acid, and vinyl acetate such that the copolymers contain no more than 15 weight percent of polymer units derived from methacrylic acid.

(b) For the purpose of this section, the methacrylic acid copolymers with ethylene and isobutyl acrylate consist of basic copolymers produced by the copolymerization of methacrylic acid. ethylene, and isobutyl acrylate such that the copolymers contain no less than 70 weight percent of polymer units derived from ethylene, no more than 15 weight percent of polymer units derived from methacrylic acid, and no more than 20 weight percent of polymer units derived from isobutyl acrylate. From 20 percent to 70 percent of the carboxylic acid groups may optionally be neutralized to form sodium or zinc salts.

(c) The finished food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c)