

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, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC 20408.

(2) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference in paragraph (c)(3)(i)(a)(I) of this section.

(b) For use at temperatures not to exceed 135 °C (275 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 135 °C (275 °F) for 1 hour.

(1) The chloroform-soluble fraction of the total nonvolatile extractives for containers using no adhesive, or adhesives listed in paragraphs (c)(2) (i), (ii), and (iii) of this section shall not exceed 0.0020 milligram per square centimeter (0.013 milligram per square inch) as determined by a method titled "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.

(2) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.

(3) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in

paragraph (c)(2)(vi) of this section shall not exceed 0.008 milligram per square centimeter (0.05 milligram per square inch) as determined by a method entitled, "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference in paragraph (c)(3)(i)(a)(I) of this section.

(ii) *Volatiles.* Volatile substances employed in the manufacture of high-temperature laminates must be removed to the greatest extent possible in keeping with good manufacturing practice prescribed in §174.5(a) of this chapter.

(d) Nylon 12/aluminum foil high-temperature laminates: Subject to the provisions of this paragraph, containers constructed of nylon 12 laminated to aluminum foil may be safely used at temperatures no greater than 250 °F (121 °C) in contact with all food types except those containing more than 8 percent alcohol.

(1) The container is constructed of aluminum foil to which nylon 12 film is fused. Prior to fusing the nylon 12, the aluminum foil may be optionally precoated with a coating complying with §175.300 of this chapter.

(2) Nylon 12 resin complying with §177.1500 and having an average thickness not to exceed 0.0016 inch (41 microns) may be used as the food-contact surface of the container.

(3) Container test specifications. On exposure to distilled water at 250 °F (121 °C) for 2 hours, extractives from the food-contact side of the nylon 12 multilayered construction shall not exceed 0.05 milligram per square inch (0.0078 milligram per square centimeter) as total nonvolatile extractives.

[45 FR 2843, Jan. 15, 1980, as amended at 47 FR 49639, Nov. 2, 1982; 48 FR 236, Jan. 4, 1983; 48 FR 15242, Apr. 8, 1983; 48 FR 17347, Apr. 22, 1983; 49 FR 7558, Mar. 1, 1984; 52 FR 33575, Sept. 4, 1987; 53 FR 39084, Oct. 5, 1988; 54 FR 24898, June 12, 1989; 61 FR 14481, Apr. 2, 1996; 63 FR 55943, Oct. 20, 1998; 64 FR 4785, Feb. 1, 1999; 64 FR 46272, Aug. 25, 1999]

§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

(a) The laminates identified in this section may be safely used at the specified temperatures. These articles are layered structures that are optionally

bonded with adhesives. In these articles, the food-contact layer does not function as a barrier to migration of components from non-food-contact layers. The layers may be laminated, extruded, coextruded, or fused.

(b) Laminate structures may be manufactured from:

(1) Polymers and adjuvants complying with §177.1390 of this chapter.

(2) Any polymeric resin listed in these regulations so long as the use of the resin in the structure complies with the conditions of use (food type and time/temperature) specified in the regulation for that resin.

(3) Optional adjuvant substances used in accordance with §174.5 of this chapter.

(4) The following substances in non-food-contact layers only:

Substances	Limitations
Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer (CAS Reg. No. 87365-98-8) complying with § 177.1345.	For use only with polyethylene terephthalate as the food-contact layer, complying with § 177.1630 under conditions of use C through G described in table 2 of § 176.170(c) of this chapter. Laminate structures, when extracted with 8 percent ethanol at 150 °F for 2 hours shall not yield <i>m</i> -pheny lenedioxy- <i>O</i> , <i>O</i> '-diethyl isophthalate or cyclic bis(ethylene isophthalate) in excess of 7.8 micrograms/square decimeter (0.5 microgram/square inch) of food-contact surface.
Nylon 6/12 resins complying with § 177.1500(b), item 13.2, of this chapter (CAS Reg. No. 25191-04-2).	For use with nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam and 0.04 milligram of <i>omega</i> -lauro lactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.

Substances	Limitations
Nylon 6/66 resins complying with § 177.1500(b), item 4.2 of this chapter (CAS Reg. 24993-04-2).	For use only with: 1. Nonalcoholic foods at temperatures not to exceed 82.2 °C (180 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam per square inch when extracted with water at 82.2 °C (180 °F) for 5 hours. 2. Nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate films with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.
Nylon 6/69 resins complying with § 177.1500(b), item 14, of this chapter (CAS Reg. No. 51995-62-1).	For use with nonalcoholic foods under conditions of use B, C, D, E, F, G, and H described in table 2 of § 176.170 of this chapter. Laminate structures with authorized food-contact materials may contain nylon 6/69 resins provided that the nitrogen content of aqueous extracts of a representative laminate (obtained at 100 °C (212 °F) for 8 hours) does not exceed 15 micrograms per square centimeter (100 micrograms per square inch).

[52 FR 33575, Sept. 4, 1987, as amended at 53 FR 19772, May 31, 1988; 57 FR 43399, Sept. 21, 1992; 58 FR 32610, June 11, 1993; 62 FR 53957, Oct. 17, 1997]

§ 177.1400 Hydroxyethyl cellulose film, water-insoluble.

Water-insoluble hydroxyethyl cellulose film may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Water-insoluble hydroxyethyl cellulose film consists of a base sheet manufactured by the ethoxylation of cellulose under controlled conditions, to which may be added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in parts 170 through 189 of this chapter, the optional substances used