

§ 177.1400

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

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

in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances permitted to be used in water-insoluble hydroxyethyl cellulose film by prior sanction or approval and under conditions specified in such sanctions or approval, and substances listed in part 181, subpart B of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of water-insoluble hydroxyethyl cellulose film.

(4) Substances identified in and used in compliance with § 177.1200(c).

(c) Any substance employed in the production of the water-insoluble hydroxyethyl cellulose film described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

§ 177.1420 Isobutylene polymers.

Isobutylene polymers may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, isobutylene polymers are those produced as follows:

(1) Polyisobutylene produced by the homopolymerization of isobutylene such that the finished polymers have a molecular weight of 750,000 (Flory) or higher.

(2) Isobutylene-isoprene copolymers produced by the copolymerization of isobutylene with not more than 3 molar percent of isoprene such that the finished polymers have a molecular weight of 300,000 (Flory) or higher.

(3) Chlorinated isobutylene-isoprene copolymers produced when isobutylene-isoprene copolymers (molecular weight 300,000 (Flory) or higher) are modified by chlorination with not more than 1.3 weight-percent of chlorine.

(b) The polymers identified in paragraph (a) of this section may contain optional adjuvant substances required

in the production of the polymers. The optional adjuvant substances required in the production of the polymers may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and aluminum chloride.

(c) The provisions of this section are not applicable to polyisobutylene used in food-packaging adhesives complying with §175.105 of this chapter.

§177.1430 Isobutylene-butene copolymers.

Isobutylene-butene copolymers identified in paragraph (a) of this section may be safely used as components of

articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, isobutylene-butene copolymers consist of basic copolymers produced by the copolymerization of isobutylene with mixtures of *n*-butenes such that the finished basic copolymers contain not less than 45 weight percent of polymer units derived from isobutylene and meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (c) of this section.

(b) *Specifications:*

Isobutylene-butene copolymers	Molecular weight (range)	Viscosity (range)	Maximum bromine value
1. Used as release agents in petroleum wax complying with § 178.3710 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
2. Used as plasticizers in polyethylene or polypropylene complying with § 177.1520, and in polystyrene complying with § 177.1640.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
3. Used as components of nonfood articles complying with §§ 175.300, 176.170, 176.210, 177.2260(d)(2), 177.2800, and 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
4. Used as production aids in the manufacture of expanded (foamed) polystyrene articles complying with §177.1640 of this chapter.	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90.
5. Used in release coatings on backings or linings for pressure-sensitive adhesive labels complying with § 175.125 of this chapter.	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90

(c) The analytical methods for determining whether isobutylene-butene copolymers conform to the specifications in paragraph (b) are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by American Society for Testing and Materials (ASTM) method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined 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) *Viscosity.* Viscosity shall be determined by ASTM method D445-74, "Test

for Kinematic Viscosity of Transparent and Opaque Liquids," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(3) *Maximum bromine value.* Maximum bromine value shall be determined by ASTM method D1492-78, "Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(d) The provisions of this section are not applicable to isobutylene-butene copolymers used as provided under §175.105 of this chapter.

[52 FR 11641, Apr. 10, 1987, as amended at 63 FR 36175, July 2, 1998]