Food and Drug Administration, HHS

§177.1050

Acrylonitrile/styrene copolymers	Maximum re- sidual acrylo- nitrile mon- omer content of finished article	Nitrogen con- tent of co- polymer	Maximum extractable fractions at specified temperatures and times	Conformance with certain specifications
 Acrylonitrile/styrene copolymer consisting of the copolymer pro- duced by polymerization of 66– 72 parts by weight of acrylo- nitrile and 28–34 parts by weight of styrene; for use with food of Types VI-A and VI-B identified in table 1 of §176.170(c) of this chapter under conditions of use C, D, E, F, G described in table 2 of §176.170(c) of this chapter. 	0.10 ppm (calculated on the basis of the weight of the ac- rylonitrile copolymer resin in the finished ar- ticles). ²	17.4 to 19 pct.	Total nonvolatile extractives not to exceed 0.01 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at $66 ^{\circ}C (150 ^{\circ}F)$. The extracted copolymer shall not exceed 0.001 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at $66 ^{\circ}C (150 ^{\circ}F)$.	Maximum carbon di- oxide permeability at 23 °C (73 °F) for the finished article is 0.04 barrer. ³

¹Use methods for determination of residual acrylonitrile monomer content, maximum extractable fraction, number average molecular weight, and solution viscosity, tilled: "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method"; "Infrared Spectrophotometric Determination of Polymer Extracted from Barex 210 Resin Pellets"; "Procedure for the Determination of Molecular Weights of Acrylonitrile/Styrene Copolymers," and "Analytical Method for 10% Solution Viscosity of Tyril," which are incorproated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy, College Park, MD 20740, 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 As determined by the method tilled "Headspace Sampling and Gas-Solif Chromatographic Determination of Residual Acrylonitrile Copolyemr Solutions," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy, College Park, MD 20740, 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.
³ As determined on appropriately shaped test samples of the article or acrylonitrile copolyemr layer in a multilayer construction by ASTM method Dr.1434-82, "Standard Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy, College Park, MD 20710, and the American Society for Testing Materials, 100 Barr Harbor D

(d) Interim listing. Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

(e) Acrylonitrile copolymer identified in this section may be used to fabricate beverage containers only if they comply with the specifications of item 3 in paragraph (c) of this section.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 49 FR 36643, Sept. 19, 1984; 52 FR 33803, Sept. 8, 1987]

§177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.

Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer identified in this section may be safely used as a component of bottles intended for use with foods identified in table I of §176.170(c) of this chapter as Type VI-B under conditions for use E, F, or G described in table 2 of §176.170(c) of this chapter.

(a) Identity. For the purpose of this section, acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer consists of a blend of:

(1) 82-88 parts by weight of a matrix copolymer produced by polymerization of 77-82 parts by weight of acrylonitrile and 18-23 parts of styrene; and

(2) 12-18 parts by weight of a grafted rubber consisting of (i) 8-12 parts of butadiene/styrene elastomer containing 77-82 parts by weight of butadiene and 18-23 parts by weight of styrene and (ii) 4-6 parts by weight of a graft copolymer consisting of 70-77 parts by weight of acrylonitrile and 23-30 parts by weight of styrene.

(b) Adjuvants. The modified copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part. and the following:

§177.1050

Substances	Limitations		
n-Dodecylmercaptan	The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercapto-propionitrile as de- termined by the method titled, "De- termination of β-Dodecyl- mercaptopropionitrile in NR-16 Polymer," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, or available for inspec- tion 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.		

(c) *Specifications*. (1) Nitrogen content of the modified copolymer is in the range of 17.7-19.8 percent.

(2) Intrinsic viscosity of the matrix copolymer in butyrolactone is not less than 0.5 deciliter/gram at 35 °C, as determined by the method titled "Molecular Weight of Matrix Copolymer by Solution Viscosity," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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.

(3) Residual acrylonitrile monomer content of the modified copolymer articles is not more than 11 ppm as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call

21 CFR Ch. I (4–1–08 Edition)

202-741-6030, or go to: http:// www.archives.gov/federal_register/code_ of_federal_regulations/ibr_locations.html.

(d) Extractives limitations. The following extractives limitations are determined by an infrared spectrophotometric method titled "Infrared Spectrophotometric Determination of Polymer Extracted from Borex[®] 210 Resin Pellets," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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 __loca-

tions.html. Copies are applicable to the modified copolymers in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10:

(1) The extracted copolymer shall not exceed 2.0 ppm in aqueous extract obtained when a 100-gram sample of copolymer is extracted with 250 milliliters of freshly distilled water at reflux temperature for 2 hours.

(2) The extracted copolymer shall not exceed 0.5 ppm in *n*-heptane when a 100gram sample of the basic copol-ymer is extracted with 250 milliliters spectral grade *n*-heptane at reflux temperature for 2 hours.

(e) Accelerated extraction end test. The modified copolymer shall yield acrylonitrile monomer not in excess of 0.4 ppm when tested as follows:

(1) The modified copolymer shall be in the form of eight strips $\frac{1}{2}$ inch by 4 inches by .03 inch.

(2) The modified copolymer strips shall be immersed in 225 milliliters of 3 percent acetic acid in a Pyrex glass pressure bottle.

(3) The pyrex glass pressure bottle is then sealed and heated to $150 \,^{\circ}$ F in either a circulating air oven or a thermostat controlled bath for a period of 8 days.

(4) The Pyrex glass pressure bottle is then removed from the oven or bath

Food and Drug Administration, HHS

and cooled to room temperature. A sample of the extracting solvent is then withdrawn and analyzed for acrylonitrile monomer by а gas chromatographic method titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies, are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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 loca-

tions.html.

(f) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

(g) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42
FR 48544, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982; 54 FR 24898, June 12, 1989]

§177.1060 *n*-Alkylglutarimide/acrylic copolymers.

n-Alkylglutarimide/acrylic copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and part 174 of this chapter.

(a) Identity. For the purpose of this section, *n*-alkylglutarimide/acrylic copolymers are copolymers obtained by reaction of substances permitted by \$177.1010(a) (1), (2), and (3) with the following substance: Monomethylamine (CAS Reg. No. 74-89-5), to form *n*-methylglutarimide/acrylic copolymers.

(b) Adjuvants. The copolymers identified in paragraph (a) of this section may contain adjuvant substances required in their production. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations, as set forth in part 174 of this chapter.

(c) *Specifications*. Maximum nitrogen content of the copolymer determined by micro-Kjeldahl analysis, shall not exceed 8 percent.

(d) Limitations. (1) The n-alkylglutarimide/acrylic copolymers in the finished form in which they shall contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature described in tables 1 and 2 of \$176.170(c) of this chapter, shall yield extractives not to exceed the limitations of \$177.1010(b) of this chapter, when prepared as strips, as described in \$177.1010(c)(2) of this chapter.

(2) The *n*-alkylglutarimide/acrylic copolymers shall not be used as polymer modifiers in vinyl chloride homo- or copolymers.

(e) Conditions of use. The nalkylglutarimide/acrylic copolymers are used as articles or components of articles (other than articles composed of vinyl chloride homo- or copolymers) intended for use in contact with all foods except beverages containing more than 8 percent alcohol under conditions of use D, E, F, and G as described in table 2 of 176.170(c) of this chapter.

[54 FR 20382, May 11, 1989, as amended at 58 FR 17098, Apr. 1, 1993]

§177.1200 Cellophane.

Cellophane may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been 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 this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in §181.22 of this chapter.