§ 177.1050  
21 CFR Ch. I (4–1–09 Edition)

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<th>Acrylonitrile/styrene copolymers</th>
<th>Maximum residual acrylonitrile monomer content of finished article</th>
<th>Nitrogen content of copolymer</th>
<th>Maximum extractable fractions at specified temperatures and times</th>
<th>Conformance with certain specifications</th>
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<td>3. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile 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.</td>
<td>0.10 ppm (calculated on the basis of the weight of the acrylonitrile copolymer resin in the finished articles).2</td>
<td>17.4 to 19 pct.</td>
<td>Total nonvolatile extracts not to exceed 0.01 mg/m² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). The extracted copolymer shall not exceed 0.001 mg/m² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F).1.</td>
<td>Maximum carbon dioxide permeability at 23 °C (73 °F) for the finished article is 0.04 barrer.3</td>
</tr>
</tbody>
</table>


2 As determined on appropriately shaped test samples of the article or acrylonitrile copolymer layer in a multilayer construction by ASTM method D–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 20740, and 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.

3 As determined on appropriately shaped test samples of the article or acrylonitrile copolymer layer in a multilayer construction by ASTM method D–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 20740, and 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.

(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.


§ 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:
Food and Drug Administration, HHS

Substances Limitations

n-Dodecylmercaptan The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercapto-propionitrile as determined by the method titled, “Determination of β-Dodecylmercapto-propionitrile 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 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.

(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 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 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_locations.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 100-gram sample of the basic copolymer is extracted with 250 milliliters of 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: “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_locations.html.

(1) The modified copolymer shall be in the form of eight strips ½ 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 °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.
and cooled to room temperature. A sample of the extracting solvent is then withdrawn and analyzed for acrylonitrile monomer by a 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_locations.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.

§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.