(d) Where acrylonitrile copolymers represent only a minor component of a polymer system, calculations based on 100 percent migration of the acrylonitrile component may be submitted in lieu of the requirements of paragraphs (a), (b), and (c) of this section in support of the continued safe use of acrylonitrile copolymers.

(e) On or before September 13, 1976, any interested person shall satisfy the Commissioner of Food and Drugs that toxicological feeding studies adequate and appropriate to establish safe conditions for the use of acrylonitrile copolymers have been, or soon will be, undertaken. Toxicity studies of acrylonitrile monomer shall include: (1) Lifetime feeding studies with a mammalian species, preferably with animals exposed in utero to the chemical, (2) studies of multigeneration reproduction with oral administration of the test material, (3) assessment of teratogenic and mutagenic potentials, (4) subchronic oral administration in a nonrodent mammal, (5) tests to determine any synergistic toxic effects between acrylonitrile monomer and cyanide ion, and (6) a literature search on the effects of chronic ingestion of hydrogen cyanide. Data on levels of acrylamide extractable from acrylonitrile copolymers shall also be submitted.

Protocols of testing should be submitted for review to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(f) Acrylonitrile copolymers may be used in contact with food only if authorized in parts 174 through 179 or §181.32 of this chapter, except that other uses of acrylonitrile copolymers in use prior to June 14, 1976, may continue under the following conditions:

(1) On or before August 13, 1976, each use of acrylonitrile copolymers in a manner not authorized by §181.32 of this chapter or parts 174 through 179 of this chapter shall be the subject of a notice to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Such notice shall be accompanied by a statement of the basis, including any articles and correspondence, on which the user in good faith believed the use to be prior-sanctioned. The Commissioner of Food and Drugs shall, by notice in the Federal Register, identify any use of acrylonitrile copolymers not in accordance with this paragraph. Those uses are thereafter unapproved food additives and consequently unlawful.

(2) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall be the subject of a petition submitted on or before December 13, 1976, in accordance with §171.1 of this chapter, unless an extension of time is granted by the Food and Drug Administration for good cause shown. Any application for extension shall be by petition submitted in accordance with the requirements of part 10 of this chapter. If a petition is denied, in whole or in part, those uses subject to the denial are thereafter unapproved food additives and consequently unlawful.

(3) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall meet the acrylonitrile monomer extraction limitation set forth in paragraph (a) of this section and shall be subject to the requirements of paragraph (b) of this section.

(g) In addition to the requirements of this section, the use of acrylonitrile copolymers shall comply with all applicable requirements in other regulations in this part.

§180.25 Mannitol.

(a) Mannitol is the chemical 1,2,3,4,5,6-hexahexanol (C$_{6}$H$_{14}$O$_{6}$) a hexahydric alcohol, differing from sorbitol principally by having a different optical rotation. Mannitol is produced by one of the following processes:

(1) The electrolytic reduction or transition metal catalytic hydrogenation of sugar solutions containing glucose or fructose.

(2) The fermentation of sugars or sugar alcohols such as glucose, sucrose, fructose, or sorbitol using the yeast Zygosaccharomyces rouxii.

(3) A pure culture fermentation of sugars such as fructose, glucose, or maltose using the nonpathogenic,
§ 180.30  Brominated vegetable oil.

The food additive brominated vegetable oil may be safely used in accordance with the following prescribed conditions:

(a) The additive complies with specifications prescribed in the “Food Chemicals Codex,” 3d Ed. (1981), pp. 40–41, which is incorporated by reference, except that free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.

(b) The additive is used on an interim basis as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 parts per million in the finished beverage, pending the outcome of additional toxicological studies on which periodic reports at 6-month intervals are to be furnished and final results submitted to the Food and Drug Administration promptly after completion of the studies.