§ 177.1520(a) of this chapter. The finished film may contain one or more of the following added substances:

Substances	Limitations
Amides of erucic, linoleic, oleic, palmitic, and stearic acid	Not to exceed 1 pct by weight of the polymer.
BHA as described in § 172.110 of this chapter	Do.
BHT as described in § 172.115 of this chapter	Do.
Calcium and sodium propionates	Do.
Petroleum wax as described in § 178.3710 of this chapter	Do.
Polypropylene, noncrystalline, as described in § 177.1520(c) of this chapter.	Not to exceed 2 pct by weight of the polymer.
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in § 172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer.
Triethylene glycol as described in § 178.3740(b) of this chapter	Do.
Mineral oil as described in § 178.3620 (a) or (b) of this chapter	Do.

(ii) Polyethylene terephthalate film prepared from the basic polymer as described in § 177.1630(e)(4)(ii) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iii) Nylon 6 films prepared from the nylon 6 basic polymer as described in § 177.1500(a)(6) of this chapter and meeting the specifications of item 6.1 of the table in § 177.1500(b) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iv) Vinyl chloride-vinyl acetate copolymer film prepared from the basic copolymer containing 88.5 to 90.0 weight percent of vinyl chloride with 10.0 to 11.5 weight percent of vinyl acetate and having a maximum volatility of not over 3.0 percent (1 hour at 105 °C) and viscosity not less than 0.30 determined by ASTM method D1243–79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," Method A, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(9) of this section. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

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

[42 FR 14635, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984; 54 FR 7405, Feb. 21, 1989; 54 FR 24899, June 12, 1989; 59 FR 14551, Mar. 29, 1994; 61 FR 14246, Apr. 1, 1996; 66 FR 10575, Feb. 16, 2001]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

Subpart A—General Provisions

Sec.
180.1 General.

Subpart B—Specific Requirements for Certain Food Additives

180.22 Acrylonitrile copolymers.
180.25 Mannitol.
180.30 Brominated vegetable oil.
180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

EDITORIAL NOTE: Nomenclature changes to part 180 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 180.1 General.

(a) Substances having a history of use in food for human consumption or in food contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is not conclusive. An interim food additive regulation for the use of any such substance may be promulgated in this subpart when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the

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public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study.

(b) No interim food additive regulation may be promulgated if the new information is conclusive with respect to the question raised or if there is a reasonable likelihood that the substance is harmful or that continued use of the substance will result in harm to the public health.

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

(1) Use of the substance in food or food contact surfaces must comply with whatever limitations the Commissioner deems to be appropriate under the circumstances.

(2) Within 60 days following the effective date of the regulation, an interested person shall satisfy the Commissioner in writing that studies adequate and appropriate to resolve the questions raised about the substance have been undertaken, or the Food and Drug Administration may undertake the studies. The Commissioner may extend this 60-day period if necessary to review and act on proposed protocols. If no such commitment is made, or adequate and appropriate studies are not undertaken, an order shall immediately be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(3) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner concludes that the studies are not being pursued promptly and diligently or if interim results indicate a reasonable likelihood that a health hazard exists, an order will promptly be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(4) If nonclinical laboratory studies are involved, studies filed with the Commissioner shall include, with respect to each study, either a statement that the study has been or will be conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(5) [Reserved]

(6) If clinical investigations involving human subjects are involved, such investigations filed with the Commissioner shall include, with respect to each investigation, a statement that the investigation either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it has been or will be conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(d) Promptly upon completion of the studies undertaken on the substance, the Commissioner will review all available data, will terminate the interim food additive regulation, and will either issue a food additive regulation or will require elimination of the substance from the food supply.

(e) The Commissioner may consult with advisory committees, professional organizations, or other experts in the field, in evaluating:

(1) Whether an interim food additive regulation is justified,

(2) The type of studies necessary and appropriate to resolve questions raised about a substance,

(3) Whether interim results indicate the reasonable likelihood that a health hazard exists, or

(4) Whether the data available at the conclusion of those studies justify a food additive regulation.

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance.

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Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in part 189 of this chapter when appropriate.

[42 FR 14636, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 42 FR 52821, Sept. 30, 1977; 46 FR 8952, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 50 FR 7492, Feb. 22, 1985; 54 FR 39634, Sept. 27, 1989]

Subpart B—Specific Requirements for Certain Food Additives

§ 180.22 Acrylonitrile copolymers.

Acrylonitrile copolymers may be safely used on an interim basis as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by a method of analysis 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.*

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food contact surface—0.003 milligram/square inch when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(b) Where necessary, current regulations permitting the use of acrylonitrile copolymers shall be revised to specify limitations on acrylonitrile/mercaptan complexes utilized in the production of acrylonitrile copolymers. Such copolymers, if they contain reversible acrylonitrile/mercaptan complexes and are used in other than repeated-use conditions, shall be tested to determine the identity of the complex and the level of the complex present in the food-contact article. Such testing shall include determination of the rate of decomposition of the complex at temperatures of 100 °F, 160 °F, and 212 °F using 3 percent acetic acid as the hydrolic agent. Acrylonitrile monomer levels, acrylonitrile/mercaptan complex levels, acrylonitrile oligomer levels, descriptions of the analytical methods used to determine the complex and the acrylonitrile migration, and validation studies of these analytical methods shall be submitted by June 9, 1977, to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, unless an extension is granted by the Food and Drug Administration for good cause shown. Analytical methods for the determination of acrylonitrile complexes with *n*-dodecyl-mercaptan, n-octyl mercaptan, and 2-mercaptoethanol, titled "Determination of β-Dodecylmercaptopropionitrile in NR–16R Aqueous Extracts" and "Measurement of β-(2-Hdroxyethylmercapto) Propionitrile in Heptane Food-Simulating Solvent,"

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are 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) The following data shall be provided for finished food-contact articles intended for repeated use:

(1) Qualitative and quantitative migration values at a time equivalent to initial batch usage, utilizing solvents and temperatures appropriate to the intended conditions of use.

(2) Qualitative and quantitative migration values at the time of equilibrium extractions, utilizing solvents and temperatures appropriate to the intended conditions of use.

(3) Data on the volume and/or weight of food handled during the initial batch time period(s), during the equilibrium test period, and over the estimated life of the food-contact surface.

(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

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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.

[42 FR 14636, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982; 54 FR 24899, June 12, 1989; 61 FR 14246, Apr. 1, 1996]

§ 180.25 Mannitol.

(a) Mannitol is the chemical 1,2,3,4,5,6,-hexanehexol ($C_6H_{14}O_6$) 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, nontoxicogenic bacterium *Lactobacillus intermedius (fermentum)*.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 188–190, which is incorporated by reference. Copies 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*.

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in § 170.3(o)(1) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutritive sweetener as defined in § 170.3(o)(21) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-finishing agent as defined in § 170.3(o)(30) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed 98 percent in pressed mints and 5 percent in all other hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 31 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 40 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 8 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, 15 percent in nonstandardized jams and jellies, commercial, as defined in § 170.3(n)(28) of this chapter, and at levels less than 2.5 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 20 grams of mannitol shall bear the statement "Excess consumption may have a laxative effect".

(f) In accordance with § 180.1, adequate and appropriate feeding studies have been undertaken for this substance. Continued uses of this ingredient are contingent upon timely and adequate progress reports of such tests, and no indication of increased risk to public health during the test period.

(g) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 61 FR 7991, Mar. 1, 1996; 69 FR 65542, Nov. 15, 2004]

§ 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.

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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.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

The food additives saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin may be safely used as sweetening agents in food in accordance with the following conditions, if the substitution for nutritive sweeteners is for a valid special dietary purpose and is in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction:

(a) Saccharin is the chemical, 1,2-benzisothiazolin-3-one - 1,1 - dioxide ($C_7H_5NO_3S$). The named salts of saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt.

(b) The food additives meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22, 62, 266–267, 297–299, which is incorporated by reference. Copies 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.*

(c) Authority for such use shall expire when the Commissioner receives the final reports on the ongoing studies in Canada and publishes an order on the safety of saccharin and its salts based on those reports and other available data.

(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce.

(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.

(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

(e) The additives are used or intended for use only for the following technological purposes:

(1) To reduce bulk and enhance flavors in chewable vitamin tablets, chewable mineral tablets, or combinations thereof.

(2) To retain flavor and physical properties of chewing gum.

(3) To enhance flavor of flavor chips used in nonstandardized bakery products.

(f) To assure safe use of the additives, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate mixes of the additive for manufacturing purposes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive, expressed as saccharin, in any intermediate mix.

(iii) Adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraphs (d) and (e) of this section.

(2) The label of any finished food product containing the additive shall bear:

(i) The name of the additive.

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(ii) The amount of the additive, calculated as saccharin, as follows:

(*a*) For beverages, in milligrams per fluid ounce;

(*b*) For cooking or table use products, in milligrams per dispensing unit;

(*c*) For processed foods, in terms of the weight or size of a serving which shall be that quantity of the food containing 30 milligrams or less of the additive.

(iii) When the additive is used for calorie reduction, such other labeling as is required by part 105 of this chapter.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 72 FR 10357, Mar. 8, 2007]

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

Subpart A—General Provisions

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181.1 General.
181.5 Prior sanctions.

Subpart B—Specific Prior-Sanctioned Food Ingredients

181.22 Certain substances employed in the manufacture of food-packaging materials.
181.23 Antimycotics.
181.24 Antioxidants.
181.25 Driers.
181.26 Drying oils as components of finished resins.
181.27 Plasticizers.
181.28 Release agents.
181.29 Stabilizers.
181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.
181.32 Acrylonitrile copolymers and resins.
181.33 Sodium nitrate and potassium nitrate.
181.34 Sodium nitrite and potassium nitrite.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14638, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 181 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 181.1 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the Act is exempt from classification as a food additive. The Commissioner will publish in this part all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the Act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of a final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the Act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in part 189 of this chapter when appropriate.

[42 FR 14638, Mar. 15, 1977, as amended at 42 FR 52821, Sept. 30, 1977; 54 FR 39635, Sept. 27, 1989]

§ 181.5 Prior sanctions.

(a) A prior sanction shall exist only for a specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958.

(b) The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but

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