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.

(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.


PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

Subpart A—General Provisions

Sec. 181. General.
181.5 Prior sanctions.

Subpart B—Specific Prior-Sanctioned Food Ingredients

181.22 Certain substances employed in the manufacture of food-packaging materials.
§ 181.5 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 not from the other adulteration or the misbranding provisions of the Act.

(c) All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingredient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the Act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in part 184 of this chapter or substances in food-contact surfaces in part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in parts 172 and 173 of this chapter or food additives in food-contact surfaces in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, the Commissioner shall, if he is aware of any prior sanction for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate

§ 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.
§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the substances listed in §§181.23, 181.24, 181.25, 181.26, 181.27, 181.28, 181.29, and 181.30 in the manufacture of packaging materials. So used, these substances are not considered “food additives,” within the meaning of section 201(a) of the Act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this subpart, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified in this subpart.

[42 FR 56728, Oct. 28, 1977]

§ 181.23 Antimycotics.

Substances classified as antimycotics, when migrating from food-packaging material shall include:

Calcium propionate.
Methylparaben (methyl p-hydroxybenzoate).
Propylparaben (propyl p-hydroxybenzoate).
Sodium benzoate.
Sodium propionate.
Sorbic acid.


§ 181.24 Antioxidants.

Substances classified as antioxidants, when migrating from food-packaging material (limit of addition to food, 0.005 percent) shall include:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Dilauryl thiodipropionate.
Distearyl thiodipropionate.
Gum guaiac.
Nordihydroguairetic acid.
Propyl gallate.
Thiodipropionic acid.
2,4,5-Trihydroxy butyrophenone.


§ 181.25 Driers.

Substances classified as driers, when migrating from food-packaging material shall include:

Cobalt caprylate.
Cobalt linoleate.
Cobalt naphthenate.
Cobalt tallate.
Iron caprylate.
Iron linoleate.
Iron naphthenate.
Iron tallate.
Manganese caprylate.
Manganese linoleate.
Manganese naphthenate.
Manganese tallate.


§ 181.26 Drying oils as components of finished resins.

Substances classified as drying oils, when migrating from food-packaging material (as components of finished resins) shall include:
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§ 181.27 Plasticizers.

Substances classified as plasticizers, when migrating from food-packaging material shall include:

- Acetyl tributyl citrate.
- Acetyl triethyl citrate.
- p-tert-Butylphenyl salicylate.
- Butyl stearate.
- Butylphthalyl butyl glycolate.
- Dibutyl sebacate.
- Di-(2-ethylhexyl) phthalate (for foods of high water content only).
- Diethyl phthalate.
- Dilsobutyl adipate.
- Dilsocetyl phthalate (for foods of high water content only).
- Diphenyl-2-ethylhexyl phosphate.
- Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).
- Ethylphthalyl ethyl glycolate.
- Glycerol monooleate.
- Monoisopropyl citrate.
- Mono, di-, and tristearyl citrate.
- Triacetin (glycerol triacetate).
- Triethyl citrate.
- 3-(2-Xenolyl)-1,2-epoxypropane.

§ 181.28 Release agents.

Substances classified as release agents, when migrating from food-packaging material shall include:

- Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups, no more than 18 percent loss in weight after heating 4 hours at 200 °C; viscosity 300 centisokes, 600 centisokes at 25 °C, specific gravity 0.96 to 0.97 at 25 °C, refractive index 1.400 to 1.404 at 25 °C).
- Linoleamide (linoleic acid amide).
- Oleamide (oleic acid amide).
- Palmitamide (palmitic acid amide).
- Stearamide (stearic acid amide).

§ 181.29 Stabilizers.

Substances classified as stabilizers, when migrating from food-packaging material shall include:

- Aluminum mono-, di-, and tristearate.
- Ammonium citrate.
- Ammonium potassium hydrogen phosphate.
- Calcium glycerophosphate.
- Calcium phosphate.
- Calcium hydrogen phosphate.
- Calcium oleate.
- Calcium acetate.
- Calcium carbonate.
- Calcium ricinoleate.
- Calcium stearate.
- Disodium hydrogen phosphate.
- Magnesium glycerophosphate.
- Magnesium stearate.
- Magnesium phosphate.
- Magnesium hydrogen phosphate.
- Mono-, di-, and trisodium citrate.
- Mono-, di-, and tripotassium citrate.
- Potassium oleate.
- Potassium stearate.
- Sodium pyrophosphate.
- Sodium stearate.
- Sodium tetracyrophosphate.
- Stannous stearate (not to exceed 50 parts per million tin as a migrant in finished food).
- Zinc orthophosphate (not to exceed 50 parts per million zinc as a migrant in finished food).
- Zinc resinate (not to exceed 50 parts per million zinc as a migrant in finished food).

§ 181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.

Substances used in the manufacture of paper and paperboard products used in food packaging shall include:

- Aliphatic polyoxyethylene ethers.∗
- 1-Alkyl (C₆₋C₁₈)3-amino-3-aminopropane monoacetate.∗
- Borax or boric acid for use in adhesives, sizes, and coatings.∗
- Butadiene-styrene copolymer.
- Chromium complex of perfluoro-octane sulfonyl glycine for use on paper and paperboard which is waxed.∗
- Disodium cyanodithiolimidocarbamate with ethylene diamine and potassium N-methyl dithiocarbamate and/or sodium 2-mercaptobenzothiazole (shimicides).∗
- Ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid for use only on paper and paperboard which is waxed.∗
- Hexamethylene tetramine as a setting agent for protein, including casein.∗
- 1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C₆₋C₁₈) imidazolinium chloride.∗
- Itaconic acid (polymerized).∗

*Under the conditions of normal use, these substances would not reasonably be expected to migrate to food, based on available scientific information and data.
§ 181.32 Acrylonitrile copolymers and resins.

(a) Acrylonitrile copolymers and resins listed in this section, containing less than 30 percent acrylonitrile and complying with the requirements of paragraph (b) of this section, may be safely used as follows:

(1) Films. (i) Acrylonitrile/butadiene/styrene copolymers—no restrictions.
(ii) Acrylonitrile/butadiene copolymers—no restrictions.
(iii) Acrylonitrile/butadiene copolymer blended with vinyl chloride-vinyl acetate (optional at level up to 5 percent by weight of the vinyl chloride resin)—for use only in contact with oleomargarine.
(iv) Acrylonitrile/styrene copolymer—no restrictions.
(2) Coatings. (i) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resin—for use only on paper and paperboard in contact with meats and lard.
(ii) Polyvinyl chloride resin blended with either acrylonitrile/butadiene copolymer or acrylonitrile/butadiene styrene copolymer mixed with neoprene, for use as components of conveyor belts to be used with fresh fruits, vegetables, and fish.
(iii) Acrylonitrile/butadiene/styrene copolymer—no restrictions.
(iv) Acrylonitrile/styrene copolymer—no restrictions.
(3) Rigid and semirigid containers. (i) Acrylonitrile/butadiene/styrene copolymer—for use only as piping for handling food products and for repeated-use articles intended to contact food.
(ii) Acrylonitrile/styrene resin—no restrictions.
(iii) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resin—for use only as extruded pipe.
(b) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by using the 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.
Acrylonitrile monomer may present a hazard to health when ingested. Accordingly, any food-contact article containing acrylonitrile copolymers or resins that yield acrylonitrile monomer in excess of that amount provided for in paragraph (b) of this section shall be deemed to be adulterated in violation of section 402 of the Act.

§ 181.33 Sodium nitrate and potassium nitrate.

Sodium nitrate and potassium nitrate are subject to prior sanctions issued by the U.S. Department of Agriculture for use as sources of nitrite, with or without sodium or potassium nitrite, in the production of cured red meat products and cured poultry products.

§ 181.34 Sodium nitrite and potassium nitrite.

Sodium nitrite and potassium nitrite are subject to prior sanctions issued by the U.S. Department of Agriculture for use as color fixatives and preservative agents, with or without sodium or potassium nitrate, in the curing of red meat and poultry products.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Sec.

182.1 Substances that are generally recognized as safe.

182.10 Spices and other natural seasonings and flavorings.

182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

182.60 Synthetic flavoring substances and adjuvants.

182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

182.90 Substances migrating to food from paper and paperboard products.

182.99 Adjuvants for pesticide chemicals.

Subpart B—Multiple Purpose GRAS Food Substances

182.1045 Glutamic acid.

182.1047 Glutamic acid hydrochloride.

182.1057 Hydrochloric acid.

182.1073 Phosphoric acid.

182.1087 Sodium acid pyrophosphate.

182.1125 Aluminum sulfate.

182.1127 Aluminum ammonium sulfate.

182.1129 Aluminum potassium sulfate.

182.1131 Aluminum sodium sulfate.

182.1180 Caffeine.

182.1217 Calcium phosphate.

182.1227 Calcium carbonate.

182.1235 Caramel.

182.1320 Glycerin.

182.1440 Methylcellulose.

182.1470 Sodium caseinate.

182.1474 Sodium caseinate.

182.1480 Sodium carboxymethylcellulose.

182.1500 Monoammonium glutamate.

182.1516 Monopotassium glutamate.

182.1711 Sodium aluminosilicate.

182.1727 Sodium aluminum silicate.

182.1729 Sodium aluminum silicate, hydrated.

182.1745 Sodium aluminosilicate.

182.1748 Sodium calcium aluminosilicate, hydrated.

182.2027 Tricalcium silicate.

Subpart C—Anticaking Agents

182.2122 Aluminum calcium silicate.

182.2227 Calcium silicate.

182.2473 Magnesium silicate.

182.2727 Sodium aluminosilicate.

182.2729 Sodium calcium aluminosilicate, hydrated.

182.2906 Tricalcium silicate.

Subpart D—Chemical Preservatives

182.3013 Ascorbic acid.

182.3041 Erythorbic acid.

182.3069 Sorbic acid.

182.3109 L-thioglycolic acid.

182.3119 Ascorbyl palmitate.

182.3159 Butylated hydroxyanisole.

182.3173 Butylated hydroxytoluene.

182.3178 Calcium ascorbate.

182.3225 Calcium propionate.

182.3280 Dilauryl thiodipropionate.

182.3316 Potassium bisulfite.

182.3616 Potassium metabisulfite.

182.3728 Sodium bisulfite.

182.3740 Sodium metabisulfite.

182.3789 Sodium metabisulfite.

182.3795 Sodium metabisulfite.

182.3798 Sodium sulfite.

182.3830 Sulfur dioxide.

182.3890 Tocopherols.