Food and Drug Administration, HHS

subjected to the action of harmless bacterial starters. One or more of the articles designated in paragraphs (a)(2)(i), (ii), and (iii) of this section is intimately mixed with the edible fat and/or ingredients to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine contains not less than 15,000 international units per pound.

(b) Optional ingredients. (1) Vitamin D in such quantity that the finished oleomargarine contains not less than 1,500 international units of vitamin D per pound.

(2) Salt (sodium chloride); potassium chloride for dietary margarine or oleo-margarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers.

(5) Preservatives including but not limited to the following within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; propyl, octyl, and dodecyl gallates, ascorbyl BHT. BHA, palmitate. ascorbyl stearate, all individually or in combination, 0.02 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Color additives. For the purpose of this subparagraph, provitamin A (beta-carotene) shall be deemed to be a color additive.

(7) Flavoring substances. If the flavoring ingredients impart to the food a flavor other than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with §101.22 of this chapter.

(8) Acidulants.

(9) Alkalizers.

(c) *Nomenclature*. The name of the food for which a definition and standard of identity are prescribed in this section is "margarine" or "oleomargarine".

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. For the purposes of this section the use of the term "milk" unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient statement. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

[42 FR 14478, Mar. 15, 1977, as amended at 47
FR 11834, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 58 FR 21649, Apr. 23, 1993; 59 FR 26939, May 25, 1994; 63 FR 14035, Mar. 24, 1998]

PART 168—SWEETENERS AND TABLE SIRUPS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

Sec.

- 168.110 Dextrose anhydrous.
- 168.111 Dextrose monohydrate.
- 168.120 Glucose sirup.
- 168.121 Dried glucose sirup.
- 168.122 Lactose.
- 168.130 Cane sirup.
- 168.140 Maple sirup.
- 168.160 Sorghum sirup.
- 168.180 Table sirup.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: $42\,$ FR 14479, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

§168.110 Dextrose anhydrous.

(a) Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization and conforms to the specifications of §168.111, except that the total solids content is not less than 98.0 percent m/m.

(b) The name of the food is "Dextrose anhydrous" or "Anhydrous dextrose" or alternatively, "_____ sugar anhydrous" or "Anhydrous sugar", with the blank to be filled with the name of the

food source, for example, "Corn sugar anhvdrous".

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§168.111 Dextrose monohydrate.

(a) Dextrose monohydrate is purified and crystallized D-glucose containing one molecule of water of crystallization with each molecule of D-glucose.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 90.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 99.5 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 0.25 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 20 mg/kg.

(c) The name of the food is "Dextrose monohydrate" or "Dextrose" or alter-"_____sugar monohydrate" sugar", with the blank to be natively, " or " filled with the name of the food source, example, "Corn sugar for monohydrate" or "Corn sugar"

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b) (1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTER-NATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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.

(1) Total solids content, 31.005.

(2) Reducing sugar content, section 31.220(a).

(3) Sulfated ash content, section 31.216.

21 CFR Ch. I (4-1-23 Edition)

(4) Sulfur dioxide content, sections 20.106-20.111.

[42 FR 14479, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§168.120 Glucose sirup.

(a) Glucose sirup is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 70.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 20.0 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 1.0 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg.

(c) The name of the food is "Glucose sirup". When the food is derived from a specific type of starch, the name may alternatively be " sirup". the blank to be filled in with the name of the starch. For example, "Corn sirup". "Wheat sirup", "Tapioca sirup". When the starch is derived from sorghum grain, the alternative name of the food is "Sorghum grain sirup". The word "sirup" may also be spelled "syrup".

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b)(1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTER-NATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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.

 $(\overline{1})$ Total solids content, sections 31.208-31.209.

(2) Reducing sugar content, section 31.220(a).

Food and Drug Administration, HHS

(3) Sulfated ash content, section 31.216.

(4) Sulfur dioxide content, sections 20.106-20.111.

[42 FR 14479, Mar. 15, 1977, as amended at 47
FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§168.121 Dried glucose sirup.

(a) Dried glucose sirup is glucose sirup from which the water has been partially removed and conforms to the specifications of §168.120, except that:

(1) The total solids content is not less than 90.0 percent m/m when the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 88.0 percent m/m, calculated on a dry basis; or

(2) The total solids content is not less than 93.0 percent m/m when the reducing sugar content, (dextrose equivalent) expressed as D-glucose, is less than 88.0 percent m/m, calculated on a dry basis.

(b) The name of the food is "Dried glucose sirup" or "Glucose sirup solids". When the food is derived from a specific type of starch, the name may alternatively be "Dried sirup" or sirup solids", the blank to be filled in with the name of the starch; for example, "Dried corn sirup", "Corn sirup solids", "Dried wheat sirup", "Wheat sirup solids", "Dried tapioca sirup", "Tapioca sirup solids". When the starch is derived from sorghum grain, the alternative name of the food is "Dried sorghum grain sirup" or "Sorghum grain sirup solids". The word "sirup" may also be spelled "syrup".

§168.122 Lactose.

(a) Lactose is the carbohydrate normally obtained from whey. It may be anhydrous or contain one molecule of water of crystallization or be a mixture of both forms.

(b) The food shall meet the following specifications:

(1) The lactose content is not less than 98.0 percent, mass over mass (m/ m), calculated on a dry basis.

(2) The sulfated ash content is not more than 0.3 percent, m/m, calculated on a dry basis.

(3) The pH of a 10.0-percent m/m solution is not less than 4.5 nor more than 7.5.

(4) The loss on drying for 16 hours at 120 $^{\circ}\mathrm{C}$ is not more than 6.0 percent, m/ m.

(c) The name of the food is "Lactose" or, alternatively, "Milk sugar".

(d) The methods of analysis in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(5) of this section are to be used to determine whether the food meets the requirements of paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section. The methods are contained in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th Ed. (1984), including the 4th Supp. (1988), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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 http://www.archives.gov/fedto: eral_register/code_of_federal_regulations/ *ibr locations.html*.

 $(\overline{1})$ Lactose content, sections 31.064 to 31.071, "Purity of Lactose, Liquid Chromatographic Method," First Action, 14th Ed. (1984), pp. 583 and 584.

(2) Lactose content, sections 31.064 to 31.071, "Purity of Lactose, Liquid Chromatographic Method," "Changes in Official Methods of Analysis," 14th Ed., 4th Supp. (1988), p. 212. This reference recognizes the change in status of the method from first action to final action.

(3) Sulfated ash content, section 31.014, "Ash of Sugars and Sirups," Final Action, Sulfated Ash, 14th Ed. (1984), p. 575.

(4) pH, section 14.022, "pH of Flour, Potentiometric Method," Final Action, except that a 10-percent m/m solution of lactose in water is used for the determination, 14th Ed. (1984), p. 252.

(5) Loss on drying at 120 °C, section 31.070, 14th Ed. (1984), p. 584.

[42 FR 14479, Mar. 15, 1977, as amended at 47
FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 55 FR 8459, Mar. 8, 1990; 63 FR 14035, Mar. 24, 1998]

§168.130 Cane sirup.

(a) Cane sirup is the liquid food derived by concentration and heat treatment of the juice of sugarcane (*Saccharum officinarum* L.) or by solution in water of sugarcane concrete made from such juice. It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in cane sirup are:

(1) Salt.

(2) Preservatives.

(3) Defoaming agents.

(c) The name of the food is "Cane sirup" or "Sugar cane sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§168.140 Maple sirup.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar (mapel concrete) made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in maple sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(c) The name of the food is "Maple sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) Label declaration. Each of the ingredients used in the food shall be de-

21 CFR Ch. I (4–1–23 Edition)

clared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2896, Jan. 6, 1993]

§168.160 Sorghum sirup.

(a) Sorghum sirup is the liquid food derived by concentration and heat treatment of the juice of sorghum cane (sorgos) (Sorghum vulgare). It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in sorghum sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(4) Enzymes.

(5) Anticrystallizing agents.

(6) Antisolidifying agents.

(c) The name of the food is "Sorghum sirup" or "Sorghum". Alternatively, the word "sirup" may be spelled "syrup".

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§168.180 Table sirup.

(a) Table sirup is the liquid food consisting of one or more of the optional sweetening ingredients provided for in paragraph (b)(1) of this section. The food contains not less than 65 percent soluble sweetener solids by weight and is prepared with or without added water. It may contain one or more of the optional ingredients prescribed in paragraphs (b)(2) through (12) of this section. All ingredients from which the food is fabricated shall be safe and suitable. (Vitamins, minerals, and protein added for nutritional purposes and artificial sweeteners are not considered to be suitable ingredients for this food.)

Food and Drug Administration, HHS

(b) The optional ingredients that may be used in table sirup are:

(1) One or more of the nutritive carbohydrate sweeteners provided for in this paragraph (b)(1). When a sweetener provided for in paragraph (b)(1)(i) or (ii) of this section is used it shall constitute not less than 2 percent by weight of the finished food.

(i) The sirups identified by §§ 168.130, 168.140, and 168.160, except that the use of any such ingredient is so limited that the finished food does not meet the requirement prescribed for any sirup by § 168.130, § 168.140, or § 168.160.

(ii) Honey.

(iii) Other nutritive carbohydrate sweeteners.

(2) Butter, in a quantity not less than 2 percent by weight of the finished food.

(3) Edible fats and oils, except that, in products designated as "buttered sirups", butter as provided for in paragraph (b)(2) of this section is the only fat that may be used.

(4) Emulsifiers or stabilizers or both.

(5) Natural and artificial flavorings, either fruit or nonfruit, alone or in carriers.

(6) Color additives.

(7) Salt.

(8) Chemical preservatives.

(9) Viscosity adjusting agents.

(10) Acidifying, alkalizing, or buffering agents.

(11) Defoaming agents.

(12) Any other ingredient (e.g., shredded coconut, ground orange peel) that is not incompatible with other ingredients in the food.

(c) Except as provided for in this paragraph and in paragraphs (d) (2) and (3) of this section, the name of the food is "Table sirup", "Sirup", "Pancake sirup", "Waffle sirup", "Pancake and waffle sirup", or " sirup", the blank being filled in with the word or words that designate the sweetening ingredient that characterizes the food, except "maple", "cane", or "sorghum" alone, such sirups being required to comply in all respects with §§168.130, 168.140, and 168.160, respectively, and in the case of more than one sweetening ingredient, in descending order of predominance by weight in the food. The type shall be of uniform style and size.

(1) When one of the sweeteners constitutes at least 80 percent of the total sweetener solids, the name of the food may be designated as the corresponding sirup, for example, "Corn sirup", provided that the name is immediately and conspicuously followed, without intervening written, printed, or graphic matter, by the statement " as part of the name, the "with blank being filled in with the name or names of each additional sweetening ingredient present, stated in a clear legible manner in letters of uniform style and size not less than one-half the height of, nor larger than, the letters used in the name of the principal sweetener.

(2) When butter is used, as provided for in paragraph (b)(2) of this section, the name of the food may be "Buttered

", the blank being filled in with the name otherwise prescribed in this paragraph. The percentage by weight of butter present shall be declared as part of the name of the food as prescribed by part 102 of this chapter.

(3) Alternatively, the word "sirup" may be spelled "syrup".

(d)(1) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) A statement (other than in the ingredient listing) or a vignette identifying a flavor may be included on the label only if such flavor contributes the primary recognizable flavor that characterizes the sirup. When maple, honey, or both maple and honey are represented as the characterizing flavors, the total quantity of maple sirup or honey, singly, or of maple sirup and honey in combination, shall be not less than 10 percent by weight of the finished food. The presence of any natural or artificial flavor in the food shall be declared on the label as prescribed by the applicable sections of part 101 of this chapter.

(3) The percentage of any optional ingredient used shall be declared as part of the name of the food as prescribed by part 102 of this chapter when all of the following conditions apply to the use of the ingredient:

Pt. 169

(i) It is one of the characterizing ingredients permitted by paragraphs (b)(1) (i) and (ii) of this section.

(ii) The ingredient is either named on the label other than in the list of ingredients or is suggested by vignette or other labeling.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

PART 169—FOOD DRESSINGS AND **FLAVORINGS**

Subpart A—General Provisions

Sec. 169.3 Definitions.

Subpart B-Requirements for Specific Standardized Food Dressings and Flavorings

- 169.140 Mayonnaise.
- 169.150 Salad dressing.
- 169.175Vanilla extract.
- Concentrated vanilla extract. 169.176
- 169 177 Vanilla flavoring.
- Concentrated vanilla flavoring. 169.178169.179
- Vanilla powder.
- Vanilla-vanillin extract. 169.180
- 169 181 Vanilla-vanillin flavoring.
- 169.182 Vanilla-vanillin powder.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14481, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§169.3 Definitions.

For the purposes of this part:

(a) The term vanilla beans means the properly cured and dried fruit pods of Vanilla planifolia Andrews and of Vanilla tahitensis Moore.

(b) The term unit weight of vanilla beans means, in the case of vanilla beans containing not more than 25 percent moisture, 13.35 ounces of such beans; and, in the case of vanilla beans containing more than 25 percent moisture, it means the weight of such beans equivalent in content of moisture-free vanilla-bean solids to 13.35 ounces of vanilla beans containing 25 percent moisture. (For example, one unit weight of vanilla beans containing 33.25 percent moisture amounts to 15 ounces.) The moisture content of vanilla beans is determined by the meth-

21 CFR Ch. I (4-1-23 Edition)

od prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 7.004 and 7.005, which is incorporated by reference, except that the toluene used is blended with 20 percent by volume of benzene and the total distillation time is 4 hours. Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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 $\mathbf{g}\mathbf{0}$ to: http:// www.archives.gov/federal register/

code of federal regulations/

ibr locations.html. To prepare samples for analysis, the pods are chopped into pieces approximately ¹/₄-inch in longest dimension, using care to avoid moisture change.

(c) The term unit of vanilla constituent means the total sapid and odorous principles extractable from one unit weight of vanilla beans, as defined in paragraph (b) of this section, by an aqueous alcohol solution in which the content of ethyl alcohol by volume amounts to not less than 35 percent.

[42 FR 14481, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart B—Requirements for Spe-Standardized cific Food **Dressings and Flavorings**

§169.140 Mayonnaise.

(a) Description. Mayonnaise is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section. One or more of the ingredients specified in paragraph (d) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (d)(7) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. Mayonnaise contains not less than 65 percent by weight of vegetable oil.