§ 172.375 Potassium iodide.

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.379 Vitamin D₂.

Vitamin D₂ may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₂, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. Vitamin D₂ is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization.

(b) Vitamin D₂ meets the specifications of the Food Chemicals Codex, 6th ed. (2008), pp. 1013 and 1014, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: http://www.usp.org). You may inspect a copy at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071, or at the National Archives and Records Administration.

Food and Drug Administration, HHS § 172.380

Vitamin D₃ may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₃, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D₃ meets the specifications of the Food Chemicals Codex, 5th ed. (2004), pp. 498–499, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or 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 additive may be used as follows:

1. At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 33 percent of the reference daily intake (RDI) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

2. At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

3. At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

4. At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

5. At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under §170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§133.165 and 133.183 of this chapter, and those defined by standard of identity in §133.148 of this chapter.

(74 FR 11022, Mar. 16, 2009)

§ 172.380 Vitamin D₃.

Vitamin D₃ may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₃, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D₃ meets the specifications of the Food Chemicals Codex, 5th ed. (2004), pp. 498–499, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or 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 additive may be used as follows:

1. At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 33 percent of the reference daily intake (RDI) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

2. At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

3. At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

4. At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

5. At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under §170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§133.165 and 133.183 of this chapter, and those defined by standard of identity in §133.148 of this chapter.

(68 FR 9003, Feb. 27, 2003, as amended at 70 FR 36025, June 22, 2005; 70 FR 37257, June 29, 2005; 70 FR 69438, Nov. 16, 2005)