§ 172.375  21 CFR Ch. I (4–1–14 Edition)

Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(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.
§ 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, 7th ed. (2010), pp. 1080–1081, 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 United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address http://www.usp.org). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6039 or go to: http://www.archives.gov/federal-register/cfr/ibr-locations.html.

(c) The additive may be used as follows:

<table>
<thead>
<tr>
<th>Category of Food</th>
<th>Maximum Levels in Food (as Served)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soy beverages</td>
<td>50 International Units (IU)/100 grams (g)</td>
</tr>
<tr>
<td>Soy beverage products</td>
<td>89 IU/100 g</td>
</tr>
<tr>
<td>Soy-based butter substitute spreads</td>
<td>330 IU/100 g</td>
</tr>
<tr>
<td>Soy-based cheese substitutes and soy-based cheese substitute products</td>
<td>270 IU/100 g</td>
</tr>
</tbody>
</table>

§ 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)-cholestatatrien-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, 7th ed. (2010), pp. 1081–1082, 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 United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address http://www.usp.org). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6039 or go to: http://www.archives.gov/federal-register/cfr/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