Food and Drug Administration, HHS

§ 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)-cholestatetraen-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 202–741–6030 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>

[74 FR 11022, Mar. 16, 2009, as amended at 78 FR 71663, Nov. 29, 2013]
§ 172.381 Vitamin D₂ bakers yeast.

Vitamin D₂ bakers yeast may be used safely in foods as a source of vitamin D₂ and as a leavening agent in accordance with the following prescribed conditions:

(a) Vitamin D₂ bakers yeast is the substance produced by exposing bakers yeast (Saccharomyces cerevisiae) to ultraviolet light, resulting in the photolytic conversion of endogenous ergosterol in bakers yeast to vitamin D₂ (also known as ergocalciferol or (9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol)).

(b) Vitamin D₂ bakers yeast may be used alone as an active dry yeast concentrate or in combination with conventional bakers yeast.

(c) The additive may be used in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods at levels not to exceed 400 International Units of vitamin D₂ per 100 grams in the finished food.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive, “vitamin D₂ bakers yeast,” in the proper order of decreasing predominance in the finished food.

[77 FR 52231, Aug. 29, 2012]

§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hake-like fish, herring of the genera Clupea, menhaden, and anchovy of the species Engraulis mordax, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

1. Protein content (N × 6.25) shall not be less than 75 percent by weight of the final product, as determined by the method described in section 2.057 in “Official Methods of Analysis of the Association of Official Analytical Chemists” (AOAC), 13th Ed. (1980). Protein quality shall not be less than 100, as determined by the method described in sections 43.212–43.216 of the AOAC. The 13th Ed. is incorporated by reference, and copies may be obtained from the AOAC INTERNATIONAL, 481