§ 184.1945 Vitamin B12.

(a) Vitamin B12, also known as cyanocobalamin (C63H88CoN14O14P, CAS Reg. No. 68–0919–099), is produced commercially from cultures of Streptomyces griseus.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 343, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

1. The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

2. The ingredient is used in foods at levels not to exceed current good manufacturing practice. Vitamin B12 also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 51610, Nov. 10, 1983]

§ 184.1950 Vitamin D.

(a) Vitamin D is added to food as the following food ingredients:

(1) Crystalline vitamin D3 (C27H44O, CAS Reg. No. 50–14–6), also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The ingredient is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization.

(2) Crystalline vitamin D3 (C27H44O, CAS Reg. No. 67–97–0), 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 is also manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol. It is purified by crystallization. Vitamin D3 is the vitamin D form that is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

(3) Vitamin D2 resin and vitamin D3 resin are the concentrated forms of irradiated ergosterol (D3) and irradiated 7-dehydrocholesterol (D3) that are separated from the reacting materials in paragraphs (a)(1) and (2) of this section. The resulting products are sold as food sources of vitamin D without further purification.

(b) Vitamin D2 and vitamin D3 as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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. Vitamin D2 resin and vitamin D3 resin must be of a purity suitable for their intended use.

(c)(1) In accordance with §184.1(b)(2), the ingredients are used in food as the
sole source of added vitamin D only within the following specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum levels in food (as served)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast cereals, § 170.3(n)(4) of this chapter.</td>
<td>350 (IU/100 grams)</td>
<td>Nutrient supplement, § 170.3(c)(20) of this chapter.</td>
</tr>
<tr>
<td>Grain products and pastas, § 170.3(n)(23) of this chapter.</td>
<td>90 (IU/100 grams)</td>
<td>Do.</td>
</tr>
<tr>
<td>Milk products, § 170.3(n)(30) of this chapter.</td>
<td>42 (IU/100 grams)</td>
<td>Do.</td>
</tr>
<tr>
<td>Milk products, § 170.3(n)(31) of this chapter.</td>
<td>89 (IU/100 grams)</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(2) Vitamin D may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(3) Vitamin D may be used in margarine in accordance with § 166.110 of this chapter.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

§ 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006–44–8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.