Food and Drug Administration, HHS

§ 184.1976

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. Do.</td>
</tr>
<tr>
<td>Grain products and pastas, § 170.3(n)(23) of this chapter. Milk, § 170.3(n)(30) of this chapter. Milk products, § 170.3(n)(31) of this chapter.</td>
<td>90 (IU/100 grams)</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>42 (IU/100 grams)</td>
<td>Do.</td>
</tr>
<tr>
<td></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, Washington, DC 20018, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6000, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
§ 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008–015–869) is obtained from the leaves and buds of the Brazilian wax palm Copernicia cerifera Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C24 to C32 normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, 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 202-741–6930, or go to: 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 lubricant as defined in §170.3(o)(18) of this chapter and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in §170.3(n)(6) of this chapter and in hard candy as defined in §170.3(n)(25) of this chapter.

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

[48 FR 51617, Nov. 10, 1983]

§ 184.1979 Whey.

(a)(1) Whey. Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1N hydrochloric acid per 100