this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n)(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter.

The ingredient may be used in infant formulas 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 19166, May 7, 1985]

§ 184.1461 Manganese sulfate.

(a) Manganese sulfate (MnSO₄·H₂O, CAS Reg. No. 7785–0987–097) is a pale pink, granular, odorless powder. It is obtained by reacting manganese compounds with sulfuric acid. It is also obtained as a byproduct in the manufacture of hydroquinone. Other manufacturing processes include the action of sulfur dioxide on a slurry of manganese dioxide in sulfuric acid, and the roasting of pyrolusite (MnO₂) ore with solid ferrous sulfate and coal, followed by leaching and crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 188, 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 the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n)(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter.

The ingredient may be used in infant formulas 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 19166, May 7, 1985]

§ 184.1472 Menhaden oil.

(a) Menhaden oil. (1) Menhaden oil is prepared from fish of the genus Brevoortia, commonly known as menhaden, by cooking and pressing. The resulting crude oil is then refined using the following steps: STORAGE (winterization), degumming (optional), neutralization, bleaching, and deodorization. Winterization may separate the oil and produce a solid fraction.

(2) Menhaden oil meets the following specifications:

(i) Color and state. Yellow liquid to white solid.

(ii) Odor. Odorless to slightly fishy.

(iii) Saponification value. Between 180 and 200 as determined by the American Oil Chemists’ Society Official Method Cd 3–25—“Saponification Value” (re-approved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the Office of Food Additive Safety.
Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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.

(iv) **Iodine number.** Not less than 120 as determined by the American Oil Chemists’ Society Recommended Practice Cd 11–92—‘‘Iodine Value of Fats and Oils, Cyclohexane—Acetic Acid Method,’’ which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(v) **Unsaponifiable matter.** Not more than 1.5 percent as determined by the American Oil Chemists’ Society Official Method Ca 5b–40—‘‘Unsaponifiable Matter’’ (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(vi) **Free fatty acids.** Not more than 0.1 percent as determined by the American Oil Chemists’ Society Official Method Ca 5a–40—‘‘Free Fatty Acids’’ (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(vii) **Peroxide value.** Not more than 5 milliequivalents per kilogram of oil as determined by the American Oil Chemists’ Society Official Method Cd 8–53—‘‘Peroxide Value, Acetic Acid—Chloroform Method’’ (updated 1992) or Recommended Practice Cd 8b–90—‘‘Peroxide Value, Acetic Acid—Isooctane Method’’ (updated 1992), which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(viii) **Lead.** Not more than 0.1 part per million as determined by the American Oil Chemists’ Society Official Method Ca 18c–91—‘‘Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrometry’’ (revised 1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(ix) **Mercury.** Not more than 0.5 part per million as determined by the method entitled ‘‘Biomedical Test Materials Program: Analytical Methods for the Quality Assurance of Fish Oil,’’ published in the ‘‘NOAA Technical Memorandum NMFS-SEFC-211,’’ F. M. Van Dolah and S. B. Galloway, editors, National Marine Fisheries Service, U. S. Department of Commerce, pages 71–88, November, 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(3) In accordance with §184.1(b)(2), the ingredient may be used in food only within the following specific limitations to ensure that total intake of eicosapentaenoic acid or docosahexaenoic acid does not exceed 3.0 grams/person/day:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum level of use in food (as served)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods, baking mixes, § 170.3(n)(1) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Cereals, § 170.3(n)(4) of this chapter</td>
<td>4.0 percent</td>
</tr>
<tr>
<td>Cheese products, § 170.3(n)(5) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Chewing gum, § 170.3(n)(6) of this chapter</td>
<td>3.0 percent</td>
</tr>
<tr>
<td>Condiments, § 170.3(n)(8) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Confections, frostings, § 170.3(n)(9) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Dairy product analogs, § 170.3(n)(10) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Egg products, § 170.3(n)(11) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Fats, oils, § 170.3(n)(12) of this chapter</td>
<td>12.0 percent</td>
</tr>
<tr>
<td>Fish products, § 170.3(n)(13) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Frozen dairy desserts, § 170.3(n)(20) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Gelatin, puddings, § 170.3(n)(22) of this chapter</td>
<td>1.0 percent</td>
</tr>
<tr>
<td>Gravies, sauces, § 170.3(n)(24) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Hard candy, § 170.3(n)(25) of this chapter</td>
<td>10.0 percent</td>
</tr>
<tr>
<td>Jams, jellies, § 170.3(n)(28) of this chapter</td>
<td>7.0 percent</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS

§ 184.1490

Methylparaben.

(a) Methylparaben is the chemical methyl p-hydroxybenzoate. It is produced by the methanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined 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 ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in

(ix) Mercury. Not more than 0.5 part per million.

(x) Arsenic (as As). Not more than 0.1 part per million.

(xi) Lead. Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in §170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term “hydrogenated,” or if it is partially hydrogenated, the name shall include the term “partially hydrogenated,” in accordance with §101.4(b)(14) of this chapter.

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl p-hydroxybenzoate. It is produced by the methanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined 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 ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in

(ix) Mercury. Not more than 0.5 part per million.

(x) Arsenic (as As). Not more than 0.1 part per million.

(xi) Lead. Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in §170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term “hydrogenated,” or if it is partially hydrogenated, the name shall include the term “partially hydrogenated,” in accordance with §101.4(b)(14) of this chapter.

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl p-hydroxybenzoate. It is produced by the methanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined 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 ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in

(ix) Mercury. Not more than 0.5 part per million.

(x) Arsenic (as As). Not more than 0.1 part per million.

(xi) Lead. Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in §170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term “hydrogenated,” or if it is partially hydrogenated, the name shall include the term “partially hydrogenated,” in accordance with §101.4(b)(14) of this chapter.

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl p-hydroxybenzoate. It is produced by the methanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined 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 ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in