Food and Drug Administration, HHS

§ 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 Ca 3–25—“Saponification Value” (reapproved 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 1d–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 6b–53—“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.

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

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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 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.

(ix) Mercury. Not more than 0.5 part per million as determined by the method entitled ‘‘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.

(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>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>
<tr>
<td>Meat products, §170.3(n)(29) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Milk products, §170.3(n)(31) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Nonalcoholic beverages, §170.3(n)(3) of this chapter</td>
<td>0.5 percent</td>
</tr>
<tr>
<td>Nut products, §170.3(n)(32) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Pastas, §170.3(n)(23) of this chapter</td>
<td>2.0 percent</td>
</tr>
<tr>
<td>Plant protein products, §170.3(n)(33) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Poultry products, §170.3(n)(34) of this chapter</td>
<td>3.0 percent</td>
</tr>
<tr>
<td>Processed fruit juices, §170.3(n)(35) of this chapter</td>
<td>1.0 percent</td>
</tr>
<tr>
<td>Processed vegetable juices, §170.3(n)(36) of this chapter</td>
<td>1.0 percent</td>
</tr>
<tr>
<td>Snack foods, §170.3(n)(37) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>Soft candy, §170.3(n)(38) of this chapter</td>
<td>4.0 percent</td>
</tr>
<tr>
<td>Soup mixes, §170.3(n)(40) of this chapter</td>
<td>3.0 percent</td>
</tr>
<tr>
<td>Sugar substitutes, §170.3(n)(42) of this chapter</td>
<td>10.0 percent</td>
</tr>
<tr>
<td>Sweet sauces, toppings, syrups, §170.3(n)(43) of this chapter</td>
<td>5.0 percent</td>
</tr>
<tr>
<td>White granulated sugar, §170.3(n)(41) of this chapter</td>
<td>4.0 percent</td>
</tr>
</tbody>
</table>

(4) To ensure safe use of the substance, menhaden oil shall not be used in combination with any other added oil that is a significant source of eicosapentaenoic acid or docosahexaenoic acid.

(b) Hydrogenated and partially hydrogenated menhaden oils. (1) Partially hydrogenated and hydrogenated menhaden oils are prepared by feeding hydrogen gas under pressure to a converter containing crude menhaden oil and a nickel catalyst. The reaction is begun at 150 to 160 °C and after 1 hour the temperature is raised to 180 °C until the desired degree of hydrogenation is reached. Hydrogenated menhaden oil is fully hydrogenated.

(2) Partially hydrogenated and hydrogenated menhaden oils meet the following specifications:

(i) Color. Opaque white solid.

(ii) Odor. Odorless.

(iii) Saponification value. Between 180 and 200.

(iv) Iodine number. Not more than 119 for partially hydrogenated menhaden oil and not more than 10 for fully hydrogenated menhaden oil.

(v) Unsatifiable matter. Not more than 1.5 percent.

(vi) Free fatty acids. Not more than 0.1 percent.

(vii) Peroxide value. Not more than 5 milliequivalents per kilogram of oil.
(viii) Nickel. Not more than 0.5 part per million.
(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 this regulation do not exist or have been waived.
§184.1498 Microparticulated protein product.
(a) Microparticulated protein product is prepared from egg whites or milk protein or a combination of egg whites and milk protein. These protein sources may be used alone or in combination with other safe and suitable ingredients to form the microparticulated product. The mixture of ingredients is high-shear heat processed to achieve a smooth and creamy texture similar to that of fat. Safe and suitable ingredients used in the preparation of the microparticulated protein product must be used in compliance with the limitations of the appropriate regulations in parts 172, 182, and 184 of this chapter.
(b) The ingredient is used in food in accordance with §184.1(b)(2) at levels not to exceed current good manufacturing practice. The affirmation of the use of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following conditions of use:
(1) The ingredient is used in food as a thickener as defined in §170.3(o)(28) of this chapter or as a texturizer as defined in §170.3(o)(32) of this chapter.
(2) The ingredient is used in frozen dessert-type products except that the ingredient may not be used to replace the milk fat required in standardized frozen desserts.
(3) The name of the ingredient used in the ingredient statement on both bulk and packaged food must include the source of the protein (e.g., “microparticulated egg white protein”), followed by a parenthetical listing of each of the ingredients in the microparticulated protein product, in descending order of predominance. Microparticulated protein product must be used in accordance with this requirement or its addition to food will be considered by FDA to constitute the use of an unapproved food additive (see §184.1(b)(2)).
[55 FR 6391, Feb. 23, 1990]