

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 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" (re-approved 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-SEFDC-211," F. M. Van Dolah and S. B. Galloway, editors, National Marine Fisheries Service, U. S.

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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:

Category of food	Maximum level of use in food (as served)
Baked goods, baking mixes, § 170.3(n)(1) of this chapter.	5.0 percent
Cereals, § 170.3(n)(4) of this chapter	4.0 percent
Cheese products, § 170.3(n)(5) of this chapter.	5.0 percent
Chewing gum, § 170.3(n)(6) of this chapter ..	3.0 percent
Condiments, § 170.3(n)(8) of this chapter	5.0 percent
Confections, frostings, § 170.3(n)(9) of this chapter.	5.0 percent
Dairy product analogs, § 170.3(n)(10) of this chapter.	5.0 percent
Egg products, § 170.3(n)(11) of this chapter	5.0 percent
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula.	12.0 percent
Fish products, § 170.3(n)(13) of this chapter	5.0 percent
Frozen dairy desserts, § 170.3(n)(20) of this chapter.	5.0 percent
Gelatins, puddings, § 170.3(n)(22) of this chapter.	1.0 percent
Gravies, sauces, § 170.3(n)(24) of this chapter.	5.0 percent
Hard candy, § 170.3(n)(25) of this chapter	10.0 percent
Jams, jellies, § 170.3(n)(28) of this chapter ..	7.0 percent
Meat products, § 170.3(n)(29) of this chapter	5.0 percent
Milk products, § 170.3(n)(31) of this chapter	5.0 percent
Nonalcoholic beverages, § 170.3(n)(3) of this chapter.	0.5 percent
Nut products, § 170.3(n)(32) of this chapter ..	5.0 percent
Pastas, § 170.3(n)(23) of this chapter	2.0 percent
Plant protein products, § 170.3(n)(33) of this chapter.	5.0 percent
Poultry products, § 170.3(n)(34) of this chapter.	3.0 percent
Processed fruit juices, § 170.3(n)(35) of this chapter.	1.0 percent
Processed vegetable juices, § 170.3(n)(36) of this chapter.	1.0 percent
Snack foods, § 170.3(n)(37) of this chapter ..	5.0 percent
Soft candy, § 170.3(n)(38) of this chapter	4.0 percent
Soup mixes, § 170.3(n)(40) of this chapter ...	3.0 percent
Sugar substitutes, § 170.3(n)(42) of this chapter.	10.0 percent
Sweet sauces, toppings, syrups, § 170.3(n)(43) of this chapter.	5.0 percent
White granulated sugar, § 170.3(n)(41) of this chapter.	4.0 percent

(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) *Unsaponifiable 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.

[62 FR 30756, June 5, 1997, as amended at 70 FR 14531, Mar. 23, 2005]