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.

§ 184.1498 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)).

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§ 184.1505 Mono- and diglycerides.

(a) Mono- and diglycerides consist of a mixture of glyceryl mono- and diesters, and minor amounts of triesters, that are prepared from fats or oils or fat-forming acids that are derived from edible sources. The most prevalent fatty acids include lauric, linoleic, myristic, oleic, palmitic, and stearic. Mono- and diglycerides are manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The products are further purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90 percent-by-weight glycerides.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 201, which is incorporated by reference in accordance with 5 U.S.C. 552(a). 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:


(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 in food as a dough strengthener as defined in § 170.3(o)(6) of this chapter; an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter; a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; a surface-active agent as defined in § 170.3(o)(29) of this chapter; a surface-finishing

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