

Food and Drug Administration, HHS

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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. Copies of the methods are available from the sources listed in the table in this paragraph:

Specification	Limit	Method Cited	Source for Obtaining Method
(1) Sucrose esters	Not less than 90%	"Method for Analyzing the Purity of Sucrose Fatty Acid Esters," issued by Mitsubishi Chemical Corp., June 17, 1998.	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.
(2) Mono-, di-, and tri-esters ...	Not more than 45%	"Method for Measuring the Ester Distribution of Sucrose Oligoesters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.
(3) Tetra-, penta-, hexa-, and hepta-esters.	Not less than 50%	Do.	Do.
(4) Octa-esters	Not more than 40%	Do.	Do.
(5) Free Sucrose	Not more than 0.5%	"Free Sucrose Method," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.
(6) Acid Value	Not more than 4.0	"Acid Value," Appendix VII, Method I (Commercial Fatty Acids), in the <i>Food Chemicals Codex</i> , 4th ed. (1996), p. 820.	National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418 (Internet: http://www.nap.edu).
(7) Residue on Ignition	Not more than 0.7%	"Residue on Ignition, Appendix IIC, Method I, in the <i>Food Chemicals Codex</i> , 4th ed. (1996), pp. 751-752, (using a 1-gram sample).	Do.
(8) Residual Methanol	Not more than 10 milligrams/kilogram.	Method listed in the monograph for "Sucrose Fatty Acid Esters" in the First Supplement to the 4th ed. of the <i>Food Chemicals Codex</i> (1997), pp. 44-45.	Do.
(9) Residual Dimethyl Sulf-oxide.	Not more than 2.0 milligrams/kilogram.	Do.	Do.
(10) Residual Isobutyl Alcohol	Not more than 10 milligrams/kilogram.	Do.	Do.
(11) Lead	Not more than 1.0 milligram/kilogram.	"Atomic Absorption Spectrophotometric Graphite Furnace Method," Method I, in the <i>Food Chemicals Codex</i> , 4th ed. (1996), pp. 763-765.	Do.

(c) The additive is used as an emulsifier (as defined in §170.3(o)(8) of this chapter) or stabilizer (as defined in §170.3(o)(28) of this chapter) in chocolate and in butter-substitute spreads, at a level not to exceed 2.0 percent; except that the additive may not be used

in a standardized food unless permitted by the standard of identity.

[68 FR 50072, Aug. 20, 2003]

§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not

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provide for such use, in accordance with the following prescribed conditions:

(a) The additive consists of one of the following:

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage that contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 10 centipoises for a 10 percent by weight aqueous solution at 25 degrees C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy (OC₃H₆OH) content of 5 to 16 percent weight in weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener in food, in accordance with good manufacturing practice. The additive also may be used as a binder in dietary supplements, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981, as amended at 76 FR 41689, July 15, 2011]

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula [C₆H_(10-x-y)O₅(CH₃)_x(C₂H₅)_y]_n, where *x* is the number of methyl groups and *y* is the number of ethyl groups. The average value of *x* is 0.3 and the average value of *y* is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH₃, and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC₂H₅, both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004-65-3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows: