Food and Drug Administration, HHS

§ 172.870 Hydroxypropyl cellulose.

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

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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 (OC\textsubscript{3}H\textsubscript{6}OH) 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.

(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.

### §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:

#### Use and Limitations

- **Hard candy production**—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.
- **Vitamin and mineral tablets**—As a component of protective coatings.

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