(1) The ingredient is used as a curing and pickling agent as defined in §170.3(o)(5) of this chapter, leavening agent as defined in §170.3(o)(17) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and sequestrant as defined in §170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

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

§ 184.1322 Wheat gluten.

(a) Wheat gluten (CAS Reg. No. 8002–80–0) is the principal protein component of wheat and consists mainly of gliadin and glutenin. Wheat gluten is obtained by hydrating wheat flour and mechanically working the sticky mass to separate the wheat gluten from the starch and other flour components. Vital gluten is dried gluten that has retained its elastic properties.

(b) The ingredient must be of a purity suitable for its intended use.

(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 as a dough strengtheners as defined in §170.3(o)(6) of this chapter; a formulation aid as defined in §170.3(o)(14) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; a stabilizer and thickener as defined in §170.3(o)(28) of this chapter; a surface-finishing agent as defined in §170.3(o)(30) of this chapter; and a texturizing agent as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

§ 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is prepared by esterification of commercial oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of §172.862 of this chapter. It contains glyceryl monooleate (C17H31O4, CAS Reg. No. 25496–72–4) and glyceryl esters of fatty acids present in commercial oleic acid.

(b) The ingredient must be of a purity suitable for its intended use.
§ 184.1324 Glyceryl monostearate.

(a) Glyceryl monostearate, also known as monostearin, is a mixture of variable proportions of glyceryl mono- and diglycerides. (C17H34O2, CAS Reg. No. 31566–31–1).

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The use of this ingredient in a food with no limitation other than current good manufacturing practice is based upon the following: current good manufacturing practice conditions of use:

1. The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and as a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

2. The ingredient is used in the following foods at levels not to exceed current good manufacturing practice:
   - baked goods and baking mixes as defined in §170.3(n)(1) of this chapter;
   - nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter;
   - chewing gum as defined in §170.3(n)(6) of this chapter;
   - meat products as defined in §170.3(n)(29) of this chapter.

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

§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C22 fatty acid). The mixture contains predominately glyceryl dibehenate.

(b) The ingredient meets the following specifications:

1. 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, and not more than 2.5 percent free fatty acids.

2. Behenic acid. Between 80 and 90 percent of the total fatty acid content.

3. Acid value. Not more than 1.


5. Iodine number. Not more than 3.

6. Heavy metals (as Pb). Not more than 10 parts per million.

(c) In accordance with §184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The use of this ingredient is 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 as a formulation aid, as defined in §170.3(o)(14) of this chapter.

2. The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

§ 184.1329 Glyceryl palmitostearate.

(a) Glyceryl palmitostearate is a mixture of mono-, di-, and triglycerides of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.

(b) The ingredient meets the following specifications:

1. The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

2. Heavy metals (as Pb). Not more than 10 parts per million.