

(2) The ingredient is used in food, except in infant foods and infant formulas, 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.

[49 FR 35367, Sept. 7, 1984]

#### § 184.1063 Enzyme-modified lecithin.

(a) Enzyme-modified lecithin is prepared by treating lecithin with either phospholipase A<sub>2</sub> (EC 3.1.1.4) or pancreatin.

(b) The ingredient meets the specifications in paragraphs (b)(1) through (b)(8) of this section. Unless otherwise noted, compliance with the specifications listed below is determined according to the methods set forth for lecithin in the Food Chemicals Codex, 4th ed. (1996), pp. 220–221, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) Acetone-insoluble matter (phosphatides), not less than 50.0 percent.

(2) Acid value, not more than 40.

(3) Lead, not more than 1.0 part per million, as determined by atomic absorption spectroscopy.

(4) Heavy metals (as Pb), not more than 20 parts per million.

(5) Hexane-insoluble matter, not more than 0.3 percent.

(6) Peroxide value, not more than 20.

(7) Water, not more than 4.0 percent.

(8) Lysolecithin, 50 to 80 mole percent of total phosphatides as determined by "Determination of Lysolecithin Content of Enzyme-Modified Lecithin: Method I," dated 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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 as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter.

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

[61 FR 45889, Aug. 30, 1996, as amended at 78 FR 14666, Mar. 7, 2013]

#### § 184.1065 Linoleic acid.

(a) Linoleic acid ((Z, Z)–9, 12-octadecadienoic acid (C<sub>17</sub>H<sub>31</sub>COOH) (CAS Reg. No. 60–33–3)), a straight chain unsaturated fatty acid with a molecular weight of 280.5, is a colorless oil at room temperature. Linoleic acid may be prepared from edible fats and oils by various methods including hydrolysis and saponification, the Twitchell method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

(b) The ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in §172.860(b) of this chapter.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good

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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 flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may be used in infant formula 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.

[49 FR 48534, Dec. 13, 1984, as amended at 73 FR 8606, Feb. 14, 2008]

## § 184.1069 Malic acid.

(a) Malic acid (C<sub>4</sub>H<sub>6</sub>O<sub>5</sub>, CAS Reg. No. of L-form 97-67-6, CAS Reg. No. of DL-form 617-48-1) is the common name for 1-hydroxy-1, 2-ethanedicarboxylic acid. L (+) malic acid, referred to as L-malic acid, occurs naturally in various foods. Racemic DL-malic acid does not occur naturally. It is made commercially by hydration of fumaric acid or maleic acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 183-184, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The ingredients are used as a flavor enhancer as defined in §170.3(o)(11) of this chapter, flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, and pH control agent as defined in §170.3(o)(23) of this chapter.

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(d) The ingredients are used in food, except baby food, at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 3.4 percent for nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; 3.0 percent for chewing gum as defined in §170.3(n)(6) of this chapter; 0.8 percent for gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; 6.9 percent for hard candy as defined in §170.3(n)(25) of this chapter; 2.6 percent for jams and jellies as defined in §170.3(n)(28) of this chapter; 3.5 percent for processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter; 3.0 percent for soft candy as defined in §170.3(n)(38) of this chapter; and 0.7 percent for all other food categories.

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

[44 FR 20656, Apr. 6, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

## § 184.1077 Potassium acid tartrate.

(a) Potassium acid tartrate (C<sub>4</sub>H<sub>5</sub>KO<sub>6</sub>, CAS Reg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 238, which is incorporated by reference. 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: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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