Food and Drug Administration, HHS

§ 184.1069

(a) Malic acid (C₄H₆O₅, 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 method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

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


§ 184.1065 Linoleic acid.

(a) Linoleic acid ((Z, Z)–9, 12-octadecadienoic acid (C₁₈H₃₀COOH) (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 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.

[61 FR 45889, Aug. 30, 1996]