

Food and Drug Administration, HHS

§ 184.1212

material at NARA, call 202-741-6030, or go to: 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 human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a firming agent as defined in §170.3(o)(10) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in §170.3(o)(12) of this chapter; a leavening agent as defined in §170.3(o)(17) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(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]

§ 184.1210 Calcium oxide.

(a) Calcium oxide (CaO, CAS Reg. No. 1305-78-8) is also known as lime, quick lime, burnt lime, or calx. It is produced from calcium carbonate, limestone, or oyster shells by calcination at temperatures of 1,700-2,450 °F.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 55, 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.

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

limitation other than 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 26714, June 29, 1984]

§ 184.1212 Calcium pantothenate.

(a) Calcium pantothenate ((C₉H₁₆NO₅)₂Ca, CAS Reg. No. of the *D*-isomer, 137-08-6) is a salt of pantothenic acid, one of the vitamins of the B complex. Only the *D*-isomer of pantothenic acid has vitamin activity, although both the *D*-isomer and the *DL*-racemic mixture of calcium pantothenate are used in food. Commercial calcium pantothenate is prepared synthetically from isobutyraldehyde and formaldehyde via 1,1-dimethyl-2-hydroxy-propionaldehyde and pantolactone.

(b) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 56, 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.

(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 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. Calcium pantothenate 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.

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

[48 FR 51908, Nov. 15, 1983]

§ 184.1221 Calcium propionate.

(a) Calcium propionate (C₆H₁₀CaO₄, CAS Reg. No. 4075-81-4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 60, 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.

(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 an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; cheeses as defined in §170.3(n)(5) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; and jams and jellies as defined in §170.3(n)(28) of this chapter.

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

[49 FR 13141, Apr. 3, 1984]

21 CFR Ch. I (4-1-11 Edition)

§ 184.1229 Calcium stearate.

(a) Calcium stearate (Ca(C₁₇H₃₅COO)₂, CAS Reg. No. 1529-23-0) is the calcium salt of stearic acid derived from edible sources. It is prepared as a white precipitate by mixing calcium chloride and sodium stearate in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 64, which is incorporated by reference, and the requirements of §172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex 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.

(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; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in foods 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.

[48 FR 52445, Nov. 18, 1983]

§ 184.1230 Calcium sulfate.

(a) Calcium sulfate (CaSO₄, CAS Reg. No. 7778-18-9 or CaSO₄·2H₂O, CAS Reg. No. 10101-41-4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by