Food and Drug Administration, HHS

bischofite. It is prepared by dissolving magnesium oxide, hydroxide, or carbonate in aqueous hydrochloric acid solution and crystallizing out magnesium chloride hexahydrate.

- (b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, 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 flavoring agent and adjuvant as defined in \$170.3(o)(12) of this chapter and 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 also 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.

 $[50~\mathrm{FR}~13559,~\mathrm{Apr.}~5,~1985;~50~\mathrm{FR}~16080,~\mathrm{Apr.}~24,~1985]$

$\S 184.1428$ Magnesium hydroxide.

- (a) Magnesium hydroxide $(Mg(OH)_2, CAS Reg. No. 1309-42-8)$ occurs naturally as the colorless, crystalline mineral brucite. It is prepared as a white precipitate by the addition of sodium hydroxide to a water soluble magnesium salt or by hydration of reactive grades of magnesium oxide.
- (b) The ingredient meets the specifications of the Food Chemicals Codex,

- 3d Ed. (1981), p. 178, 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; a pH control agent as defined in §170.3(o)(23) of this chapter; and a processing aid as defined in §170.3(o)(24) 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.

[50 FR 13559, Apr. 5, 1985, as amended at 64 FR 405, Jan. 5, 1999]

§ 184.1431 Magnesium oxide.

- (a) Magnesium oxide (MgO, CAS Reg. No. 1309-48-4) occurs naturally as the colorless, crystalline mineral periclase. It is produced either as a bulky white powder (light) or a relatively dense white powder (heavy) by heating magnesium hydroxide or carbonate. Heating these magnesium salts under moderate conditions (400° to 900 °C for a few hours) produces light magnesium oxide. Heating the salts under more rigorous conditions (1200 °C for 12 hours) produces heavy magnesium oxide. Light magnesium oxide is converted to heavy magnesium oxide by sustained heating at high temperatures.
- (b) The ingredient meets the specifications of the Food Chemicals Codex,

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3d Ed. (1981), p. 178, 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 anticaking and free-flow agent as defined in $\S170.3(o)(1)$ of this chapter; a firming agent as defined in $\S170.3(o)(10)$ of this chapter; a lubricant and release agent as defined in $\S170.3(o)(18)$ of this chapter; a nutrient supplement as defined in $\S170.3(o)(20)$ of this chapter; and a pH control agent as defined in $\S170.3(o)(23)$ of this chapter.
- (2) The ingredient is used in foods at levels not be exceed current good manufacturing practice. The ingredient also 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.

 $[50~{\rm FR}~13559,~{\rm Apr.}~5,~1985]$

§ 184.1434 Magnesium phosphate.

(a) Magnesium phosphate includes both magnesium phosphate, dibasic, and magnesium phosphate, tribasic. phosphate, Magnesium dibasic (MgHPO₄·3H₂O, CAS Reg. No. 7782-0975-094) occurs naturally as the white, crystalline mineral newberyite. It is prepared commercially as a precipitate formed by treating a solution of magnesium sulfate with disodium phosphate under controlled conditions. Magnesium phosphate, tribasic (Mg₃(PO₄)2·xH₂O, CAS Reg. No. 7757-87-

- 1) may contain 4, 5, or 8 molecules of water of hydration. It is produced as a precipitate from a solution of magnesite with phosphoric acid.
- (b) Magnesium phosphate, dibasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 179, which is incorporated by reference. Magnesium phosphate, tribasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 180, 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 and a pH control agent as defined in §170.3(o)(23) of this chapter.
- (2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also 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.

[50 FR 13560, Apr. 5, 1985, as amended at 69 FR 24512, May 4, 2004]

§ 184.1440 Magnesium stearate.

(a) Magnesium stearate $(Mg(C_{17}H_{34}COO)_2, CAS \ Reg.\ No.\ 557-04-0)$ is the magnesium salt of stearic acid. It is produced as a white precipitate by the addition of an aqueous solution of magnesium chloride to an