

also known as manganese dichloride. It is prepared by dissolving manganous oxide, pyrolusite ore (MnO_2), or reduced manganese ore in hydrochloric acid. The resulting solution is neutralized to precipitate heavy metals, filtered, concentrated, and crystallized.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(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 may be used in infant formulas 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 19165, May 7, 1985]

§ 184.1449 Manganese citrate.

(a) Manganese citrate ($Mn_3(C_6H_5O_7)_2$), CAS Reg. No. 1002-46-65) is a pale orange or pinkish white powder. It is obtained by precipitating manganese carbonate from manganese sulfate and sodium carbonate solutions. The filtered and washed precipitate is digested first with sufficient citric acid solution to form manganous citrate and then with sodium citrate to complete the reaction.

(b) FDA is developing food-grade specifications for manganese citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of 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 nutrient supplement as defined in §170.3(o)(20) 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; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n)(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter. The ingredient may be used in infant formulas 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 19166, May 7, 1985]

§ 184.1452 Manganese gluconate.

(a) Manganese gluconate ($C_{12}H_{22}MnO_{14} \cdot 2H_2O$, CAS Reg. No. 648-0953-0998) is a slightly pink colored powder. It is obtained by reacting manganese carbonate with gluconic acid in aqueous medium and then crystallizing the product.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

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