

limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as 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. The ingredient may also 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.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983, as amended at 64 FR 1760, Jan. 12, 1999]

§ 184.1535 Niacinamide.

(a) Niacinamide (C₆H₆N₂O, CAS Reg. No. 98-92-0) is the chemical 3-pyridinecarboxylic acid amide (nicotinamide). It is a white crystalline powder that is soluble in water, alcohol, ether, and glycerol. It melts between 128° and 131 °C.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, 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. The ingredient may also 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.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983]

§ 184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440-02-0) is obtained from nickel ore by transforming it to nickel sulfide (Ni₃S₂). The sulfide is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give elemental nickel.

(b) The ingredient must be of a 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 catalyst as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in § 170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

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

[48 FR 51618, Nov. 10, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1538 Nisin preparation.

(a) Nisin preparation is derived from pure culture fermentations of certain