

§ 184.1

21 CFR Ch. I (4–1–98 Edition)

184.1400 Lecithin.
 184.1408 Licorice and licorice derivatives.
 184.1409 Ground limestone.
 184.1415 Animal lipase.
 184.1425 Magnesium carbonate.
 184.1426 Magnesium chloride.
 184.1428 Magnesium hydroxide.
 184.1431 Magnesium oxide.
 184.1434 Magnesium phosphate.
 184.1440 Magnesium stearate.
 184.1443 Magnesium sulfate.
 184.1443a Malt.
 184.1444 Maltodextrin.
 184.1445 Malt syrup (malt extract).
 184.1446 Manganese chloride.
 184.1449 Manganese citrate.
 184.1452 Manganese gluconate.
 184.1461 Manganese sulfate.
 184.1472 Menhaden oil.
 184.1490 Methylparaben.
 184.1498 Microparticulated protein product.
 184.1505 Mono- and diglycerides.
 184.1521 Monosodium phosphate derivatives of mono- and diglycerides.
 184.1530 Niacin.
 184.1535 Niacinamide.
 184.1537 Nickel.
 184.1538 Nisin preparation.
 184.1540 Nitrogen.
 184.1545 Nitrous oxide.
 184.1553 Peptones.
 184.1555 Rapeseed oil.
 184.1560 Ox bile extract.
 184.1563 Ozone.
 184.1583 Pancreatin.
 184.1585 Papain.
 184.1588 Pectins.
 184.1595 Pepsin.
 184.1610 Potassium alginate.
 184.1613 Potassium bicarbonate.
 184.1619 Potassium carbonate.
 184.1622 Potassium chloride.
 184.1625 Potassium citrate.
 184.1631 Potassium hydroxide.
 184.1634 Potassium iodide.
 184.1635 Potassium iodate.
 184.1639 Potassium lactate.
 184.1643 Potassium sulfate.
 184.1655 Propane.
 184.1660 Propyl gallate.
 184.1666 Propylene glycol.
 184.1670 Propylparaben.
 184.1676 Pyridoxine hydrochloride.
 184.1685 Rennet (animal-derived) and chymosin preparation (fermentation-derived).
 184.1695 Riboflavin.
 184.1697 Riboflavin-5'-phosphate (sodium).
 184.1698 Rue.
 184.1699 Oil of rue.
 184.1721 Sodium acetate.
 184.1724 Sodium alginate.
 184.1733 Sodium benzoate.
 184.1736 Sodium bicarbonate.
 184.1742 Sodium carbonate.
 184.1751 Sodium citrate.
 184.1754 Sodium diacetate.
 184.1763 Sodium hydroxide.
 184.1764 Sodium hypophosphite.

184.1768 Sodium lactate.
 184.1769a Sodium metasilicate.
 184.1784 Sodium propionate.
 184.1792 Sodium sesquicarbonate.
 184.1801 Sodium tartrate.
 184.1804 Sodium potassium tartrate.
 184.1807 Sodium thiosulfate.
 184.1835 Sorbitol.
 184.1845 Stannous chloride (anhydrous and dihydrated).
 184.1848 Starter distillate.
 184.1851 Stearyl citrate
 184.1854 Sucrose.
 184.1857 Corn sugar.
 184.1859 Invert sugar.
 184.1865 Corn syrup.
 184.1866 High fructose corn syrup.
 184.1875 Thiamine hydrochloride.
 184.1878 Thiamine mononitrate.
 184.1890 α -Tocopherols.
 184.1901 Triacetin.
 184.1903 Tributyrin.
 184.1911 Triethyl citrate.
 184.1914 Trypsin.
 184.1923 Urea.
 184.1924 Urease enzyme preparation from *Lactobacillus fermentum*.
 184.1930 Vitamin A.
 184.1945 Vitamin B₁₂.
 184.1950 Vitamin D.
 184.1973 Beeswax (yellow and white).
 184.1976 Candelilla wax.
 184.1978 Carnauba wax.
 184.1979 Whey.
 184.1979a Reduced lactose whey.
 184.1979b Reduced minerals whey.
 184.1979c Whey protein concentrate.
 184.1983 Bakers yeast extract.
 184.1984 Zein.
 184.1985 Aminopeptidase enzyme preparation derived from *lactococcus lactis*.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14653, Mar 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this part shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as

GRAS. Ingredients affirmed as GRAS in this part are also GRAS as indirect human food ingredients, subject to any limitations prescribed in parts 174, 175, 176, 177, 178 or §179.45 of this chapter or in part 186 of this chapter. The purity specifications in this part do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with §170.30(h)(1) of this chapter.

(b) Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that a direct human food ingredient be of appropriate food grade; that it be prepared and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraph (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of these limited conditions of use, which may include the category of food(s), the technical effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that

use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with §170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(d) The listing of more than one ingredient to produce the same technological effect does not authorize use of a combination of two or more ingredients to accomplish the same technological effect in any one food at a combined level greater than the highest level permitted for one of the ingredients.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a

waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1005 Acetic acid.

(a) Acetic acid (C₂H₄O₂, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, 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) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level as served, of 0.25 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.8 percent for cheeses as defined in § 170.3(n)(5) of this chapter and dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.5 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 9.0 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 3.0 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; 0.6 percent for meat products as defined in § 170.3(n)(29) of this chapter; and 0.15 percent or less for all other food categories. The ingredient may also be used in boiler water additives at levels not to exceed current good manufacturing practice.

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

[47 FR 27814, June 25, 1982]

§ 184.1007 Aconitic acid.

(a) Aconitic acid (1,2,3-propenetricarboxylic acid (C₆H₆O₆), CAS Reg. No. 000499-12-7) occurs in the leaves and tubers of *Aconitum napellus* L. and other *Ranunculaceae*. Transaconitic acid can be isolated during sugarcane processing, by precipitation as the calcium salt from cane sugar or molasses. It may be synthesized by sulfuric acid dehydration of citric acid, but not by the methanesulfonic acid method.

(b) The ingredient meets the following specifications: