

of Agriculture. The amendments also provided for the addition of two consumer members to the 18-producer-member American Egg Board. The amendments were authorized by the June 1980 amendments to the Egg Research and Consumer Information Act (7 U.S.C. 2701 et seq.) as amended.

As provided in Section 9 of the Egg Research and Consumer Information Act (7 U.S.C. 2701 et seq.), the amendments could become effective only if approved by egg producers voting in a referendum. Under the procedure for the conduct of referenda (7 CFR 1250.200 et seq.) egg producers who, during the months of April, May, and June 1982, were engaged in commercial egg production and who were engaged in the production of eggs at the time of voting were eligible to vote. Producers with 3,000 or fewer hens and any flock of breeding hens whose production of eggs was primarily utilized for hatching of baby chicks were exempted. The referendum was conducted by mailed ballot September 3-27, 1982.

Results of the referendum show that of the 1,225 votes accepted, 499 producers voted in favor and 726 producers voted against the amendments. To go into effect, the changes had to be approved by at least two-thirds of the producers voting or by a majority of producers voting if they produced at least two-thirds of the commercial eggs of those voting. Since neither of these requirements was met, the amendments shall not become effective and the proceeding is terminated.

The failure of egg producers to approve the amendments, however, does not invalidate the current Order, as provided by 7 U.S.C. 2708.

Signed at Washington, D.C., on October 25, 1982.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182, 184, and 186

[Docket No. 81N-0382]

Magnesium Gluconate, Potassium Gluconate, Sodium Gluconate, Zinc Gluconate, and Gluconic Acid; Proposed GRAS Status as Direct and Indirect Human Food Ingredients

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that sodium gluconate is generally recognized as safe (GRAS) as a direct human food ingredient, and that gluconic acid is GRAS as an indirect human food ingredient. FDA is proposing not to affirm zinc gluconate as GRAS as a direct human food ingredient and to remove it from the list of substances that are GRAS. In addition, the agency is proposing not to affirm the GRAS status of direct food uses of magnesium gluconate or potassium gluconate. The agency previously had stated in opinion letters that it considered these substances to be GRAS. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATE: Comments by December 28, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the *Federal Register* of July 26, 1973 (38 FR 20040)) initiating this review, under which the safety of magnesium gluconate, potassium gluconate, sodium gluconate, zinc gluconate, and gluconic acid has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes to affirm the GRAS status of sodium gluconate and gluconic acid. The agency also proposes to remove zinc gluconate from the list of nutrients in Part 182 (21 CFR Part 182) because of the absence of any information that the substance is used for this purpose. FDA also proposes not to affirm the GRAS status of magnesium gluconate or potassium gluconate because of the absence of adequate food use information for these substances. The gluconate salts of iron, calcium, copper, and manganese are not covered by this proposal but will be covered in other proposals on the respective cations. Delta-gluconolactone also will be covered in a separate proposal.

Gluconic acid [CH₂OH(CHOH)₄COOH] is readily produced from glucose by mild

oxidation. The oxidation may be accomplished chemically, electrolytically, or enzymatically. Commercially, glucose is enzymatically oxidized by various microorganisms: *Aspergillus niger*, *Aspergillus fumigatus*, *Aerobacter aceti*, *Penicillium chrysogenum*, other *Penicillia*, or *Acetobacter suboxydans*. The inoculum for this fermentative oxidation is developed through successive transfers of the culture to growth vessels of increasing volume. The gluconic acid solution thus formed is purified by filtration. Sodium gluconate is formed by continuous addition of sodium hydroxide to the growing culture, yielding a gluconate salt solution of approximately 28 percent. The solution is charcoal decolorized, filtered, and evaporatively concentrated. The final product is recovered by spray drying the concentrated solution. Other gluconate salts are prepared by neutralizing a purified gluconic acid solution with a basic salt of the desired metal ion. The reaction mixtures are charcoal decolorized and filtered. The crystallized products are centrifuged out of the cooled filtrate, are washed free of impurities with water, and are dried.

A regulation published in the *Federal Register* of November 20, 1959 (24 FR 9368) listed sodium gluconate as GRAS for use as a sequestrant. Sodium gluconate is now listed for this use in § 182.6757 (21 CFR 182.6757). In addition, FDA stated in an opinion letter in 1961 that it considered sodium gluconate to be GRAS for use as a sequestrant in boiler water additives.

The U.S. Department of Agriculture (USDA) permits the use of sodium gluconate for denuding the mucous membrane from tripe and for preventing the staining of the exteriors of canned goods by cooling and retort water (9 CFR 318.7(c)(4)). USDA also permits the use of sodium gluconate in cooling and retort water for the preparation of poultry products (9 CFR 381.147(f)(3)). A Meat and Poultry Inspection proposal published in the *Federal Register* of July 15, 1977 (42 FR 38474) would permit sodium gluconate to be used in hog scalds. Sodium gluconate and gluconic acid are listed as GRAS in § 182.99 (21 CFR 182.99) as pesticide adjuvants. In several opinion letters, FDA has stated that the use of gluconic acid as a sequestrant in food and in bottle rinsing aid formulations is safe. FDA has also issued an opinion letter indicating that the use of gluconic acid as a food ingredient in dietary supplementary is GRAS.

A regulation published in the *Federal Register* of January 31, 1961 (26 FR 938)

listed zinc gluconate as a GRAS nutrient/dietary supplement. However, in a regulation published in the Federal Register of September 5, 1980, 1980 (45 FR 58837), FDA divided the nutrient/dietary supplement category into separate listings for GRAS dietary supplements and for GRAS nutrients. Therefore, zinc gluconate is now listed as GRAS in § 182.5988 (21 CFR 182.5988) for use in dietary supplements and in § 182.8988 (21 CFR 182.8988) for use in food as a nutrient. FDA has also issued opinion letters for potassium gluconate and magnesium gluconate that state that the agency considers their use as nutrients or dietary supplements to be GRAS.

In 1971, the National Academy of Sciences/National Research Council (NAS/NRC) surveyed a representative cross-section of food manufacturers to determine the specific foods in which magnesium gluconate, potassium gluconate, sodium gluconate, and zinc gluconate were used in the levels of usage. NAS/NRC combined this manufacturing information with information on consumer consumption of foods to obtain an estimate of consumer exposure to these ingredients. FDA estimates from the NAS/NRC survey that the total amount of sodium gluconate used by the U.S. food industry in 1970 was approximately 81,500 pounds. The NAS/NRC survey found that sodium gluconate is used as a sequestrant in nonalcoholic beverages and in processed fruit and fruit juices. However, NAS/NRC did not report any data on the amount of the other gluconates used in food. The survey indicated that gluconic acid was being used by the food industry, but no data on that use were submitted by industry.

Supplementary information provided by one firm indicated that gluconic acid currently is being used in a bottle rinse formulation. Another firm supplied used level information on potassium gluconate in special dietary foods in response to a request that FDA published in the Federal Register of May 31, 1977 (42 FR 27676) for additional information on gluconates. However, a subsequent followup on that information by the agency indicated that potassium gluconate is no longer used in special dietary foods.

In 1977, NAS/NRC conducted a second survey of food manufacturers and found that the U.S. food industry used 23,000 pounds of zinc gluconate in dietary supplements in 1976. No other exposure information is available for zinc gluconate. According to information supplied directly to FDA by one firm,

magnesium gluconate is also being used in dietary supplements.

Gluconate salts have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 90 abstracts was reviewed, and 28 particularly pertinent reports from the literature survey have been summarized in two scientific literature reviews.

Information from the scientific literature reviews and other sources has been summarized in a report to FDA by the Select Committee on GRAS Substances (the Select Committee), which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The members of the Select Committee have evaluated all available safety information on gluconic acid and its salts.¹ In the Select Committee's opinion:

Gluconates are useful as nutritional supplements since their high solubility allows relatively rapid absorption of the cations. Evidence suggests that any possible toxicity is a function of the cation rather than of the gluconate portion of these substances. Thus, the acute toxic responses to the various gluconate salts are comparable with other salts of the same metals and long-term toxicities seem related to the tissue deposition of these metals. These observations could have been anticipated because gluconic acid is a normal metabolic product of glucose. The amount of gluconic acid produced endogenously is many times greater than the largest amounts likely to be consumed from food. Because the toxicological activities of these gluconates appear to be a function of their cationic components, safe and

¹ "Evaluation of the Health Aspects of Sodium, Potassium, Magnesium, and Zinc Gluconates as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1978, pp. 5-8. In the past, the agency presented verbatim the Select Committee's discussion of the biological data it reviewed. However, because the Select Committee's report is available at the Dockets Management Branch and from the National Technical Information Service, and because it will represent a significant savings to the agency in publication costs, FDA has decided to discontinue presenting the discussion in the preambles to proposals that affirm GRAS status in accordance with current good manufacturing practice.

acceptable levels in foods are limited only by the nature of the specific cations.¹

The Select Committee concludes that no evidence in the available information on potassium gluconate, magnesium gluconate, sodium gluconate, and zinc gluconate demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might reasonably be expected in the future.¹

FDA has undertaken its own evaluation of the available information on these ingredients and concurs with this conclusion regarding sodium gluconate. Therefore, the agency concludes that no change in the current GRAS status of sodium gluconate is justified, and it proposes that this ingredient be affirmed as GRAS as a direct human food ingredient. The agency has also concluded that sufficient safety data exist to affirm that the use of sodium gluconate as a boiler water additive is GRAS.

However, FDA is proposing not to affirm the GRAS status of magnesium gluconate, potassium gluconate, or zinc gluconate as direct food ingredients. In previous GRAS affirmation proposals, FDA has emphasized that use information (i.e., foods to which the ingredient is added, the intended technical effect, and the levels of addition) is very important in assessing the safety of GRAS food ingredients. Because the agency does not have any evidence of conventional food² uses for zinc gluconate, magnesium gluconate, or potassium gluconate, FDA cannot evaluate the GRAS status of these food ingredients. Consequently, the agency is proposing not to affirm potassium gluconate and magnesium gluconate as GRAS for use as a nutrient or for dietary supplement use and is proposing to remove zinc gluconate from § 182.8988. FDA will reconsider the regulatory status of these ingredients if adequate use information of the type cited above is submitted as comments on this proposal. FDA is especially interested in comments on potassium gluconate because this ingredient is a possible substitute for sodium gluconate. The agency considers such a substitution desirable because of FDA's interest in reducing the level of total sodium consumption in the United States. Comments on the uses of potassium gluconate, magnesium gluconate, and zinc gluconate should provide specific

¹ *Ibid.*, p. 9.

² *Ibid.*

³ FDA is using the term "conventional food" to refer to food that would fall within any of the 43 categories listed in § 170.3(n) (21 CFR 170.3(n)).

information on use levels, food categories, and technical effects.

The only known current use of zinc gluconate and magnesium gluconate is a dietary supplement (i.e., over-the-counter vitamin preparations in forms such as capsules, tablets, liquids, wafers, etc.). The GRAS status of this use is not affected by this proposal. The agency did not request data on the amounts of these ingredients used in dietary supplements when it initiated this review. Without these data, the agency cannot evaluate the safety of using these ingredients in dietary supplements. Therefore, as indicated in the Federal Register of September 5, 1980 (45 FR 58837), FDA is taking no action on the listing of zinc gluconate in § 182.5988 for use as a dietary supplement and is not listing magnesium gluconate in Part 182 or 184 for dietary supplement use.

The only reported use for potassium gluconate is as a nutrient in special dietary foods. Because the agency has no evidence of current use for this ingredient, FDA is proposing not to affirm potassium gluconate as GRAS.

The Select Committee did not specifically address the issue of the safety of the use of gluconic acid in food. It did note, however, that gluconic acid is a normal metabolic product of glucose, and that the amount of the acid produced endogenously is many times greater than the largest amounts likely to be consumed from food. Based upon an agency review of available safety data for gluconic acid, FDA proposes to affirm the GRAS status of gluconic acid for indirect use of a component of bottle rinse formulations. However, FDA has no information that suggests that gluconic acid currently is being used as a direct food ingredient. The agency, therefore, is not proposing to affirm gluconic acid as GRAS for direct human food use.

FDA has determined that it is not necessary that gluconic acid be of food-grade purity for its indirect use in bottle wash formulations. The agency believes that the general requirements that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with § 170.30(h)(1) (21 CFR 170.30(h)(1)) and used in accordance with current good manufacturing practice are sufficient to ensure the safe use of this ingredient. Therefore, the agency has not proposed any specific purity specifications for the indirect use of gluconic acid.

Additionally, FDA is proposing not to include in the GRAS affirmation regulation for sodium gluconate the levels of use reported in the NAS/NRC food survey for this ingredient. Both

FASEB and the agency have concluded that a large margin of safety exists for the use of this substance, and that a reasonably foreseeable increase in the level of consumption of sodium gluconate will not adversely affect human health. Therefore, the agency is proposing to affirm the GRAS status of sodium gluconate when it is used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that the affirmation of the GRAS status of sodium gluconate is based on the evaluation of limited uses, the proposed regulation sets forth the technical effects and food categories that FDA evaluated.

In the Federal Register of September 7, 1982 (47 FR 39199), FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend its regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

Copies of the scientific literature reviews on gluconate salts and potassium gluconate, reports of mutagenic screening tests for sodium gluconate and zinc gluconate, and the report of the Select Committee are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Page code	Price ¹
Gluconate salts (scientific literature review).	PB228-537/AS	A03	\$6.00
Potassium gluconate (scientific literature review).	PB289-415/AS	A02	5.00
Sodium gluconate (mutagenic evaluation).	PB233-308/AS	A03	6.00
Zinc gluconate (mutagenic evaluation).	PB266-895/AS	A04	7.00
Sodium, potassium, magnesium, and zinc gluconates (Select Committee report).	PB288-675/AS	A02	5.00

¹ Price subject to change.

This proposed action does not affect the current use of magnesium gluconate, potassium gluconate, sodium gluconate, zinc gluconate, and gluconic acid for pet food or animal feed.

The format of the proposed regulations is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1757 and paragraph (b) § 186.1319 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including both the technical effect and the food categories listed. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

21 CFR Part 186

Food ingredients, Generally recognized as safe (GRAS) food ingredients, Indirect food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Parts 182, 184, and 186 be amended as follows:

**PART 182—SUBSTANCES
GENERALLY RECOGNIZED AS SAFE**

§§ 182.6757 and 182.8988 [Removed]

1. Part 182 is amended by removing § 182.6757 *Sodium gluconate* and § 182.8988 *Zinc gluconate*.

**PART 184—DIRECT FOOD
SUBSTANCES AFFIRMED AS
GENERALLY RECOGNIZED AS SAFE**

2. Part 184 is amended by adding new § 184.1757, to read as follows:

§ 184.1757 *Sodium gluconate*.

(a) Sodium gluconate ($C_6H_{11}NaO_7$, CAS Reg. No. 527-07-1) is an air-stable white powder with a slight caramel odor and a saline taste. It is prepared by the continuous sodium hydroxide neutralization of gluconic acid as it is formed during the fermentative oxidation of glucose.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 286, 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, 1100 L St. NW., 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 sequestrant as defined in § 170.3(o)(26) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter and processed fruit and fruit juices as defined in § 170.3(n)(35) of this chapter. The ingredient may also be used as a component of boiler water additives.

**PART 186—INDIRECT FOOD
SUBSTANCES AFFIRMED AS
GENERALLY RECOGNIZED AS SAFE**

3. Part 186 is amended by adding new § 186.1319, to read as follows:

§ 186.1319 *Gluconic acid*.

(a) Gluconic acid ($C_6H_{12}O_7$, CAS Reg. No. 133-42-6) is an acid sugar composed of white crystals with a mild acidic taste. In aqueous solution gluconic acid is in equilibrium with gamma- and delta-gluconolactones. Gluconic acid is

prepared by enzymatic oxidation of glucose. The strains of the microorganism used to supply the enzyme action are nonpathogenic and nontoxicogenic to man or other animals.

(b) In accordance with § 184.1(b)(1), the ingredient is used as an indirect ingredient in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used or intended for use as a component of bottle rinsing formulations.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal.

The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposed to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before December 28, 1982, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-29730 Filed 10-28-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOROffice of Surface Mining Reclamation
and Enforcement**30 CFR Part 914****Receipt of Proposed Amendment
From Indiana and Procedures for
Public Comment Period and Hearing**AGENCY: Office of Surface Mining
Reclamation and Enforcement, Interior.

ACTION: Proposed rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing procedures for the public comment period and for a public hearing on the substantive adequacy of a program amendment submitted by Indiana to satisfy one of the conditions imposed by the Secretary of the Interior on the approval of the Indiana State Program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

This notice sets forth the times and locations that the Indiana program and proposed amendment are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment and information pertinent to the public hearing.

DATES: Written comments relating to Indiana's proposed modification of its program not received on or before 4:00 p.m. on November 29, 1982 will not necessarily be considered in the Secretary's decision on whether the proposed program amendment satisfies the condition.

If requested, a public hearing will be held on November 19, 1982 beginning at 10:00 a.m. at the location shown below under "Addresses."

ADDRESSES: Written comments should be mailed or hand delivered to: Mr. Richard D. McNabb, Director, Indiana Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building and U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204, Telephone: (317) 269-2600.

If a public hearing is held, its location will be at: OSM Indiana Field Office, Conference Room, Federal Building and U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204.

FOR FURTHER INFORMATION CONTACT: Mr. Richard D. McNabb, Director, Indiana Field Office, Federal Building & U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204, Telephone: (317) 269-2600.