proposing that § 178.2010 (21 CFR 178.2010) be amended to provide for the safe use of tris (2,4-di-*tert*-butylphenyl) phosphite as an antioxidant and/or stabilizer for olefin polymers complying with § 177.1520(c) (21 CFR 177.1520(c)), without temperature limitations, intended for food-contact applications.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additve use is safe and that the regulations should be amended as set forth below. The agency further concludes that the amendment to § 178.2010 providing for the use of tris (2,4-di-*tert*-butylphenyl) phosphite as an antioxidant and/or stabilizer for ethylene-vinyl-acetate copolymers complying with § 177.1350 (21 CFR 177.1350), in FR Doc. 81–17436 appearing in the **Federal Register** of Friday, June 12, 1981 (46 FR 31007), should be republished for editorial purposes. That order inadvertently listed the additive as a new item with no reference to its current listing with six limitations.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will remove from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency previously considered the potential environmental effects of this regulation as announced in the notice of filing published in the **Federal Register**. No new information or comments have been received that would alter the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Sanitizing solutions.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 178 is amended in § 178.2010(b) by revising the fifth and sixth items, by republishing the seventh item, and by adding an eighth item in the list of limitations for "Tris(2,4-di-tert-butylphenyl) phosphite" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* *	* * *
Tris(2,4-di-*tert*-butylphenyl) phosphite (CAS Reg. No. 31570–04–4).	For use only: * * * 5. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3. 6. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, 2.3, 3.1, or 3.2. The finished polymers complying with item 2.1, 2.2, or 2.3 having a density less than 0.94 gram per cubic centimeter and a thickness greater than 0.051 millimeter (0.002 inch), shall contact food only under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter. 7. At levels not to exceed 0.2 percent by weight of ethylene-vinyl-acetate copolymers complying with § 177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter. The average thickness of such polymers in the form in which they contact fatty food shall not exceed 0.1 millimeter (0.004). 8. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 3.3 or 4. The finished polymers having a thickness greater than 0.051 millimeter (0.002 inch), shall contact food only under conditions of use E, F, and G described in table 2 of § 176.170(c)l of this chapter.
* *	* * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 30, 1982 submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective August 30, 1982.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: August 23, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–23708 Filed 8–30–82; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 182 and 184

[Docket No. 78N–0273]

GRAS Status of Hypophosphites

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug administration (FDA) is affirming that sodium hypophosphite is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency. The agency is not affirming the GRAS status of calcium, manganese, or potassium hypophosphites because there is no usage information concerning these substances.

EFFECTIVE DATE: September 30, 1982.

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: In the **Federal Register** of October 10, 1978 (43 FR 46550), FDA published a proposal to remove calcium hypophosphite, manganese hypophosphite, potassium hypophosphite, and sodium hypophosphite as substances that are GRAS for use as direct human food ingredients. The proposal was published in accordance with the announed FDA

review of the safety of GRAS and prior-sanctioned food ingredients. Although manganese hypophosphite is the only hypophosphite listed as GRAS in Part 182 (21 CFR Part 182), an opinion letter issued by the agency in 1961 acknowledged the GRAS status of calcium, potassium, and sodium hypophosphites and is the basis for including these substances in the comprehensive GRAS review.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on hypophosphites and the report of the Select Committee on GRAS Substances (the Select Committee) on hypophosphites have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents have also been made available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing the actions described above, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for these substances. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of the prior-sanctioned use could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of these substances recognized by issuance of a regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for hypophosphites were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of hypophosphites under conditions different from those set forth in this final rule has been waived.

Three comments were received in response to the proposal. A summary of these comments and the agency's response follows.

1. One comment requested a 6-month delay in the deletion of hypophosphites from the GRAS list to permit completion of research on potential future food uses of these substances.

Nearly 4 years have passed since the agency published the proposal in this matter, but no new data have been submitted. Regardless, the agency declines to delay action on the proposal. The Federal Food, Drug, and Cosmetic Act does not prevent a manufacturer from independently judging a particular use of a substance to be GRAS on its own responsibility. The GRAS review is a review of current uses of substances recognized by the agency to be GRAS or subject to a prior sanction. The GRAS petition procedure in § 170.35(c) is available to those who would like to request that FDA affirm as GRAS a substance that the agency does not currently consider GRAS, or that FDA affirm as GRAS a new use for a substance currently listed as GRAS.

2. The second comment referred to the procedure for preparing calcium hypophosphite that the agency described in the preamble to the proposal. The comment questioned whether the reactant is indeed phosphorous acid, as stated in the proposal, or whether hypophosphorous acid is the actual reactant used.

According to the Condensed Chemical Dictionary, 6th Ed., the correct reactant is elemental phosphorus rather than phosphorous acid or hypophosphorous acid. However, because FDA is not affirming the GRAS status of calcium hypophosphite, correcting the description of this aspect of the preparation procedure does not require any change in the final rule.

3. The third comment requested that sodium hypophosphite be affirmed as GRAS for use as an emulsifier/stabilizer in cod-liver oil emulsions. Further communication with the commenter revealed that sodium hypophosphite has been used in this product since early in the century. The commenter also provided information to the agency on the level of use, annual poundage used, and estimated intake based on the recommended dosage of cod-liver oil.

The agency has considered this new information in light of the Select Committee's conclusion and agrees that sodium hypophosphite should be affirmed as GRAS for this use. Accordingly, FDA is affirming that sodium hypophosphite is GRAS for use as an emulsifier/stabilizer in cod-liver oil at a current good manufacturing practice (CGMP) level. The current GMP level is 0.4 percent. Under § 184.1(a) (21 CFR 184.1(a)), substances approved as GRAS for direct food use may also be used for indirect food uses.

FDA is not adopting food-grade specifications for sodium hypophosphite at this time. The agency concludes that the affirmation of sodium hypophosphite as GRAS, without detailed specifications, does not represent a health problem. FDA will work with the Committee on Codex Specifications of the National Academy of Sciences to develop acceptable specifications for this ingredient. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if commercial sodium hypophosphite complies with the description in this final regulation and is of food-grade purity (21 CFR 170.30(b)(1) and 182.1(b)(3)).

FDA did not receive any comments providing evidence of use of calcium, manganese, or potassium hypophosphites as direct human food ingredients in response to the proposal. In addition, the 1977 National Academy of Sciences/National Research Council (NAS/NRC) industry usage survey did not report use data on any of the hypophosphites.

The format of the final regulation is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1764 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including both the technical effects and food categories listed. This change has no substantive effect but is made merely for clarity.

The agency had determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this 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.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not 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.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

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), Parts 182 and 184 are amended as follows:

§ 182.5458 [Removed]

1. Part 182 is amended by removing § 182.5458 *Manganese hypophosphite.*

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

2. Part 184 is amended by adding a new § 184.1764 to read as follows:

§ 184.1764 Sodium hypophosphite.

(a) Sodium hypophosphite (NaH_2PO_2, CAS Reg. No. 7681–53–0) is a white, odorless, deliquescent granular powder with a saline taste. It is also prepared as colorless, pearly crystalline plates. It is soluble in water, alcohol, and glycerol. It is prepared by neutralization of hypophosphorous acid or by direct aqueous alkaline hydrolysis of white phosphorus.

(b) FDA is developing food-grade specifications for sodium hypophosphite in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a suitable purity for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 emulsifier or stabilizer, as defined in §§ 170.3(o)(8) and 170.3(o)(28) of this chapter.

(2) The ingredient is used in cod-liver oil emulsions at levels not to exceed current good manufacturing practice.

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

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Effective date. This regulation is effective September 30, 1982.

Dated: August 10, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-23701 Filed 8-30-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 78N-0015]

GRAS Status of Inositol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that inositol is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: September 30, 1982.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Bureau of Foods (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 23, 1978 (43 FR 22056), FDA published a proposal to affirm that inositol is GRAS for use as a direct human food ingredient. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on inositol, data on a mutagenic evaluation, and the report of the Select Committee on GRAS Substances (the Select Committee) on inositol are available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents have also been made available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing to affirm the GRAS status of inositol, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for the substance, other than for the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of inositol recognized by issuance of an appropriate regulation under Part 181—Prior Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Parts 184 or 186) as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert the sanction at any future time.

No reports of prior-sanctioned uses for inositol were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of inositol under conditions different from those set forth in this final rule has been waived.

No comments were received in response to the proposal. Inositol is listed as a GRAS substance for dietary supplement use and nutrient use in §§ 182.5370 and 182.8370 (21 CFR 182.5370 and 21 CFR 182.8370) respectively, as described in the **Federal Register** publication of September 5, 1980 (45 FR 58837). That notice reorganized Part 182 to establish separate listings for "Dietary Supplements" and "Nutrients." Although there is no direct evidence of a dietary requirement for inositol in healthy adult humans with a mixed and varied diet, it is required by section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) as a required nutrient in infant formula that is not milk based at a minimum level of 4.0 milligrams per 100 kilocalories. FDA is reviewing all nutrient levels in infant formulas under a contract with the American Academy of Pediatrics. Any necessary modifications in the nutrient level of inositol in infant formula will be proposed by a separate rulemaking under section 412 of the act. As described in the proposal, inositol is also used in certain special dietary foods.

Therefore, FDA is removing inositol from § 182.8370 and affirming it as GRAS for use as a nutrient in infant formulas and special dietary foods. The agency is not taking any action on dietary supplement uses of inositol because there is inadequate information regarding these uses.

FDA has modified this final rule to reflect publication of specifications for inositol in the new Food Chemicals Codex, 3d edition. No differences exist between the specifications in the 2d edition, as referenced in the proposal, and those adopted in the 3d edition.

The format of the final regulation is different from that in the proposal and

in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1370 to make clear that the agency's GRAS affirmation determination is based upon current good manufacturing practice conditions of use, including both the technical effect and 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 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.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and therefore exempt.

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

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. 301(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.8370 [Removed]

1. In Part 182 by removing § 182.8379 *Inositol.*

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

2. In Part 184 by adding new § 184.1370 to read as follows:

§ 184.1370 Inositol.

(a) Inositol, or myo-inositol ($C_6H_{12}O_6$, CAS Reg. No. 87–89–8), is *cis*-1,2,3,5-*trans*-4,6-cyclohexanehexol. It occurs naturally and is prepared from an aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, 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 limitations 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 special dietary foods as defined in Part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of 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 by this section do not exist or have been waived.

Effective date. This regulation shall be effective September 30, 1982.

(Secs. 201(s), 409, 701(a) 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated August 10, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference was approved by the Director of the Office of the Federal Register on June 4, 1982, and is on file at the Office of the Federal Register.

[FR Doc. 82-23718 Filed 8-30-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 202

Prescription Drug Advertising

CFR Correction

In Title 21, Code of Federal Regulations, revised as of April 1, 1982, in Part 202, § 202.1, appearing on page 58, paragraphs (e)(6) (ii) and (vii) read incorrectly. These two paragraphs should read as follows:

(e) * * *

(6) * * *

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

* * * * *

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

BILLING CODE 1505-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 201

[Docket No. R-82-1022]

Mortgage Insurance Loans; Changes in Interest Rates

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This change in the regulations decreases the HUD/FHA maximum allowable finance charge on Title I mobile home loans, property improvement loans, and combination and mobile home lot loans as well as historic preservation loans. This action by HUD is designed to bring the maximum interest rate and financing charges on HUD/FHA-insured loans into line with market rates and help assure an adequate supply of and demand for FHA financing.

EFFECTIVE DATE: August 31, 1982.

FOR FURTHER INFORMATION CONTACT: John L. Brady, Director, Office of Title I Insured Loans, Office of Single Family Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, D.C. 20410 (202–755–6680).

SUPPLEMENTARY INFORMATION: The following miscellaneous amendments have been made to this chapter to decrease the maximum interest rate which may be charged on loans insured by this Department. Maximum finance charges on property improvement loans have been lowered from 18.50 percent to 17.50 percent, the finance charge on mobile home loans lowered from 17.50 percent to 16.50 percent, and the finance charge on combination loans for the purchase of a mobile home and a