

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 document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Food Safety and Applied Nutrition, Part 175 is amended as follows:

#### PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 175.105(c)(5) is amended by alphabetically inserting a new item in the list of substances to read as follows:

#### § 175.105 Adhesives.

\* \* \* \* \*  
(c) \* \* \*  
(5) \* \* \*

Substances	Limitations
Poly(ethylloxazoline) (CAS Reg. No. 25805-17-8)	

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-7509 Filed 4-3-87; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Part 184

[Docket No. 79N-0371/CP]

#### Potassium and Sodium Lactate; Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is affirming that potassium lactate and sodium lactate are generally recognized as safe (GRAS)

for use as direct human food ingredients. This action responds to a petition filed by Purac, Inc.

**EFFECTIVE DATE:** April 6, 1987.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Under the procedures described in 21 CFR 170.35, Purac, Inc., Arlington Heights, IL 60004, submitted a petition (GRASP 4G0292) requesting that 21 CFR Part 184 be amended to provide for the safe use of sodium lactate and potassium lactate as flavor enhancers, flavoring agents or adjuvants, humectants, and pH control agents in foods.

FDA published a notice of filing of this petition in the *Federal Register* of February 14, 1985 (50 FR 6252), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857. No comments were received in response to the agency's notice of filing.

The petition contained data and information on food-grade specifications for sodium lactate and potassium lactate and information on the current and expected uses of these ingredients in a number of food categories. The petition also referenced published articles on animal feeding studies conducted with sodium lactate. The petition, however, did not contain safety studies on the food use of potassium lactate. Nonetheless, the agency found that it could adequately evaluate the safety of the food uses of these ingredients using data already available in its files.

The data on which FDA based its evaluation of the safety of the use of both potassium lactate and sodium lactate consisted of information compiled during the comprehensive safety review of the use of lactic acid and certain lactates as direct human food ingredients. The agency referenced these data in a proposed rule in the *Federal Register* of February 25, 1983 (48 FR 8086), and subsequently affirmed the GRAS status of calcium lactate and lactic acid in a final rule published in the *Federal Register* of September 7, 1984 (49 FR 35366).

##### II. Background

The agency completed its comprehensive safety review of the GRAS status of lactic acid and calcium lactate in 1984. During the comment

period on the agency's proposal to affirm the use of lactic acid and calcium lactate as GRAS, FDA received a petition that requested that the agency also affirm the use of sodium lactate and potassium lactate as GRAS. The agency notified the petitioner by letter on July 24, 1984, that it would not address the petitioned uses of sodium lactate and potassium lactate in the final rule on lactic acid and calcium lactate because the agency needed more time to evaluate the requested uses of sodium lactate and potassium lactate. The agency also requested clarification of some data presented in the petition on the identity, specifications, safety, and methods of detection of sodium lactate and potassium lactate. The agency informed the petitioner that the data requested were essential to assess the safety of the use of these substances. FDA advised the petitioner that the agency would consider whether the requested uses of these lactates were GRAS when it was presented with the data necessary to make such an assessment.

Consequently, the petitioner submitted an amendment responding to FDA's concerns about the petition. This amendment contained the supplemental data and information requested by the agency.

##### III. Sodium Lactate and Potassium Lactate

Sodium lactate and potassium lactate are the sodium and potassium salts of lactic acid. They are prepared by neutralization of lactic acid with sodium and potassium bases. The bases used for the commercial preparation of these substances are food-grade sodium hydroxide and potassium hydroxide. Sodium and potassium lactate also occur naturally in the metabolic functions of mammalian species.

##### IV. Use and Exposure Estimates

In 1970, 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 various food ingredients, including sodium lactate and potassium lactate, were used and the levels of use. The survey revealed that sodium lactate has had only limited use as a food ingredient. No information was received from the survey on food uses of potassium lactate.

In 1982, NAS/NRC conducted a poundage update survey that found that 13 pounds of sodium lactate were used in food in 1981, and that the principal food use of this ingredient was as a

flavoring agent. No data on potassium lactate were received in the NAS/NRC 1982 poundage update.

Sodium lactate is listed in 9 CFR 318.7(c)(4) and 9 CFR 319.700 for use in margarine or oleomargarine as an acidulant. Additionally, it is listed as an optional ingredient in the preparation of mono- and diglycerides for use as emulsifiers in margarine under 21 CFR 166.110(b)(4). Sodium lactate is used in medicine as an electrolyte in injection solutions used for fluid or electrolyte replenishment and as an alkalizer for treating acidosis.

Published scientific literature included in the petition reported use of sodium lactate in other countries as a humectant to lower water activity in meat products; as a curing agent in hams; as a pH control agent in sauces, pickles, and dressings; and as a flavoring agent in imitation meat flavors (used in soups, gravies, and sauces). The Food and Agricultural Organization (FAO) Food and Nutrition Paper No. 30, which was published in 1984, listed sodium lactate as a bodying agent and antioxidant synergist for use in jams, jellies, and citrus marmalades; in edible ices and ice mixes; and in edible caseinates.

Potassium lactate is listed in 9 CFR 318.7(c)(4) and 9 CFR 319.700 for use in margarine and oleomargarine as an acidulant. The petitioned uses of potassium lactate are as a flavoring agent or adjuvant, humectant, and a pH control agent. The petitioner indicated that an anticipated major use of potassium lactate would be as a salt (sodium chloride) substitute.

The agency evaluated the safety of these ingredients at levels of use anticipated for the intended technical effects. FDA determined the estimated daily intake of sodium lactate using 1983 food consumption survey data. It calculated that the 90th percentile (data obtained from MRCA Market Census VI, 1977 and USDA 1977-1978) estimated daily intake of sodium lactate would be 1.84 grams per day.

FDA also determined the estimated daily intake of potassium lactate. The agency's first estimate was based on the assumption that potassium lactate would totally replace sodium chloride. This consumption estimate was 10 to 24 grams per day for potassium lactate. The agency recognized, however, that this number is unrealistically high because, in many instances, it is not practical to substitute potassium lactate for sodium chloride. FDA determined that a more realistic estimate for potassium lactate consumption is about 7.5 percent of the total sodium chloride consumption of 12 grams per day. On this basis, the agency calculated an

estimated daily intake for potassium lactate of 0.9 gram per day. Thus, the agency considers the 0.9 gram per day estimated daily consumption to be an accurate estimate upon which to base its safety evaluation. The agency believes that the other uses of potassium lactate are small compared to its use as a salt substitute.

The agency is confident that the estimated daily intakes that it has calculated do not understate potential exposure to sodium lactate and potassium lactate.

#### V. Safety and Technical Effects

As general evidence of safety for potassium lactate and sodium lactate, the petitioner presented copies of the report of the Select Committee on GRAS Substances on lactic acid and calcium lactate. This report contained safety data on sodium lactate. The agency evaluated the data in the report in assessing the safety of the requested uses of sodium lactate. The petitioner also submitted copies of the Select Committee reports on sodium hydroxide and potassium hydroxide. In addition, the petitioner and FDA both conducted scientific literature searches on potassium lactate and sodium lactate.

FDA has evaluated all the available information on potassium lactate and sodium lactate. Based on its review of this information (References 1 through 3), FDA finds that it can affirm that the use of these ingredients is GRAS for the following reasons:

1. There is no evidence to demonstrate that potassium lactate or sodium lactate represents a hazard to individuals when used in food in accordance with current good manufacturing practice for the purposes stated in this final rule.

2. Potassium lactate and sodium lactate are products of mammalian metabolic functions.

3. The chemistry involved in the preparation of these products is well understood. The reaction of lactic acid with sodium hydroxide or potassium hydroxide yields sodium lactate or potassium lactate plus water. No harmful products have been shown to result from this neutralized reaction.

4. Potassium lactate and sodium lactate are approved in this country for use in margarine or oleomargarine as acidulants.

When a petition is submitted seeking affirmation of GRAS status based upon scientific procedures, published studies are usually required (21 CFR 170.30(b)). The agency recognizes that, in this matter, no published studies on potassium lactate were submitted. However, FDA finds that the factors listed above, together with the other

information available on sodium lactate and on potassium lactate, as well as data available on the similar compounds lactic acid and calcium lactate, provide an appropriate basis on which to affirm the use of sodium lactate and potassium lactate as GRAS.

Additionally, the agency concludes from its assessment of data in the petition and the Select Committee's reports on lactic acid and lactates that the potassium and sodium salts of lactic acid will perform the technical effects of flavor enhancer, flavoring agent or adjuvant, humectant, and pH control agent as intended.

#### VI. Conclusion

Therefore, FDA is affirming the GRAS status of potassium lactate and sodium lactate when they are used in accordance with current good manufacturing practice under § 184.1(b)(1). To make clear, however, that the affirmation of the GRAS status of these ingredients is based on the evaluation of limited uses, the regulations set forth the technical effects of these ingredients that FDA evaluated. The use of potassium lactate and sodium lactate as an acidulant in margarine and oleomargarine is covered under the listing of pH control agent.

The agency concludes, further, that an appropriate basis on which to affirm as GRAS the general use of sodium lactate and potassium lactate in infant formula and infant foods does not exist. Although the petitioner did not request use of these lactates in infant formulas and infant foods, such use had to be considered when total dietary substitution is possible. Neither the petition nor the Select Committee's report on the comprehensive safety review of lactic acid and lactates contained information or safety data on the general use of lactates in infant formulas and foods. The agency thus concludes that exclusion for use of these ingredients in infant formulas is justified based on the absence of safety data to support such use.

Because no food-grade specifications have been accepted by FDA for potassium lactate or sodium lactate at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for these ingredients. If acceptable specifications are developed, the agency will incorporate them into these regulations at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if these ingredients comply with the description in the

regulations and are of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act, the agency considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action.

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

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which is on file with the Dockets Management Branch (address above).

#### References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated February 14, 1985, from John E. Vanderveen, Director, Division of Nutrition, to Robert L. Martin, Division of Food and Color Additives.

2. Memorandum dated February 27, 1985, from Carl B. Johnson, Division of Toxicology, to Robert L. Martin, Division of Food and Color Additives.

3. Memorandum dated December 24, 1986, from Carl B. Johnson, Division of Toxicology, to Robert L. Martin, Division of Food and Color Additives.

#### List of Subjects in 21 CFR Part 184

##### Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 184 is amended as follows:

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

1. The authority citation for 21 CFR Part 184 continues to read as follows:

**Authority:** Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

2. By adding new § 184.1639 to read as follows:

##### § 184.1639 Potassium lactate.

(a) Potassium lactate ( $C_3H_5O_3K$ , CAS Reg. No. 996-31-6) is the potassium salt of lactic acid. It is a hygroscopic, white, odorless solid and is prepared commercially by the neutralization of lactic acid with potassium hydroxide.

(b) FDA is developing food-grade specifications for potassium lactate in cooperation with the National Academy of Sciences. In the interim, this 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. This regulation does not authorize its use in infant foods and infant formulas. 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 flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

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

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

3. By adding new § 184.1768 to read as follows:

##### § 184.1768 Sodium lactate.

(a) Sodium lactate ( $C_3H_5O_3Na$ , CAS Reg. No. 72-17-3) is the sodium salt of lactic acid. It is prepared commercially by the neutralization of lactic acid with sodium hydroxide.

(b) FDA is developing food-grade specifications for sodium lactate in cooperation with the National Academy of Sciences. In the interim, this 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. This regulation does not authorize its use in infant foods and infant formulas. 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 as defined in § 170.3(o)(8) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

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

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

Dated: March 24, 1987.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-7507 Filed 4-3-87; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Part 524

#### Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification; Levamisole

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pitman-Moore, Inc., providing for use of levamisole as a pour-on liquid for treating cattle for stomach, intestinal, and lung worm infections.

**EFFECTIVE DATE:** April 6, 1987.

**FOR FURTHER INFORMATION CONTACT:** Adriano R. Gabuten, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

**SUPPLEMENTARY INFORMATION:** Pitman-Moore, Inc., Washington Crossing, NJ 08560, filed NADA 139-877 which provides for safe and effective use of a 200-milligram-per-milliliter levamisole pour-on liquid (TOTALON™) for treatment of cattle for stomach worm, intestinal worm, and lung worm infections. Levamisole is currently approved as a bolus, drench, gel, and injectable to treat cattle for stomach worm, intestinal worm, and lung worm infections. Based on the data in the NADA and additional information, the

NADA is approved and new 21 CFR 524.1240 is added to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

#### List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 524 is amended as follows:

#### PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 524 continues to read as follows:

**Authority:** Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Part 524 is amended by adding new § 524.1240 to read as follows:

##### § 524.1240 Levamisole.

(a) *Specifications.* The drug contains 200 milligrams of levamisole per milliliter of diethylene glycol monobutyl ether (DGME) solution.

(b) *Sponsor.* See 011716 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use. Cattle—(1) Amount.* 2.5 milliliters per 110 pounds (10 milligrams of levamisole per kilogram) of body weight as a single dose topically to the back of the animal.

(2) *Indications for use.* Anthelmintic effective against stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(3) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Cattle must not be slaughtered within 9 days following last treatment. Do not administer to dairy animals of breeding age. Do not treat animals before dipping or prior to exposure to heavy rain. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before using in severely debilitated animals.

Dated: March 17, 1987.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 87-7510 Filed 4-3-87; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Part 573

[Docket No. 86F-0060]

#### Food Additives Permitted in Feed and Drinking Water of Animals; Selenium

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for (1) an increase in the maximum supplementation level of selenium in complete feed for the major food-producing animals from 0.1 to 0.3 part per million; (2) a proportional increase in the limit feeding (feed supplements and salt-mineral mixtures) consumption rates for sheep and beef cattle to 0.7 milligram and 3 milligrams per head per day, respectively; (3) a proportional increase in the selenium fortification levels for salt-mineral mixtures for sheep and cattle to 90 and 120 parts per million, respectively; and (4) more flexibility in certain manufacturing controls. This action responds to a petition filed by the American Feed Industry Association, Inc.

**DATES:** Effective April 6, 1987; objections by May 6, 1987.

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

**FOR FURTHER INFORMATION CONTACT:** William D. Price, Center for Veterinary Medicine (HFV-221), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* on February 21, 1986 (51 FR 6321), FDA announced that FAP 2201 had been filed by the American Feed Industry Association, Inc., 1701 North Fort Myer Dr., Arlington, VA 22209. The petition proposes that 21 CFR 573.920 be amended (1) to increase the maximum use level of selenium in complete feed for chickens, swine, turkeys, sheep, cattle, and ducks to a level not to exceed 0.3 part per million; (2) to increase the animal unit consumption rate of feed supplements to a level not to exceed 0.7 milligram per head per day for sheep and not to exceed 3 milligrams per head per day for beef cattle; (3) to increase the selenium fortification levels and consumption rates for salt-mineral mixtures for beef cattle up to 120 parts per million in the mixture for feeding at a rate not to exceed 3 milligrams per head per day, and sheep up to 90 parts per million in the mixture for feeding at a rate not to exceed 0.7 milligram per head per day; (4) to make 1 pound the minimum amount of selenium premix (concentration of 90.8 milligrams of selenium per pound) that may be incorporated into each ton of complete feed or salt-mineral mixture for all approved animal species; and (5) to eliminate the requirement for premix manufacturers to analyze each production batch.

FDA has evaluated data and information submitted in the petition and other relevant material. The agency has concluded that Part 573 should be amended to provide for safe use of selenium as set forth below.

In accordance with § 571.1(h) (21 CFR 571.1(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 Center for Veterinary Medicine (address above) by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch