

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	S. Kruse

Food and Drug Administration

21 CFR Part 172

[Docket No. 99F-3087]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;
Sodium Stearoyl Lactylate**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in cream liqueur drinks. This action is in response to a petition filed by the American Ingredients Co.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3047.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** on September, 13, 1999 (64 FR 49495), FDA announced that a food additive petition (FAP 9A4684) had been filed by the American Ingredients Co., 3947 Broadway, Kansas City, MO 64111. The petition proposed to amend the food additive regulations in § 172.846 *Sodium stearoyl lactylate* (21 CFR 172.846) to provide for the safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in cream liqueur drinks.

II. Conclusions

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of sodium stearoyl lactylate is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 172.846 should be amended as set forth below.

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 Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9A4684. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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 are to be submitted and are to 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 172

Food additives, Reporting and recordkeeping requirements.

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, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

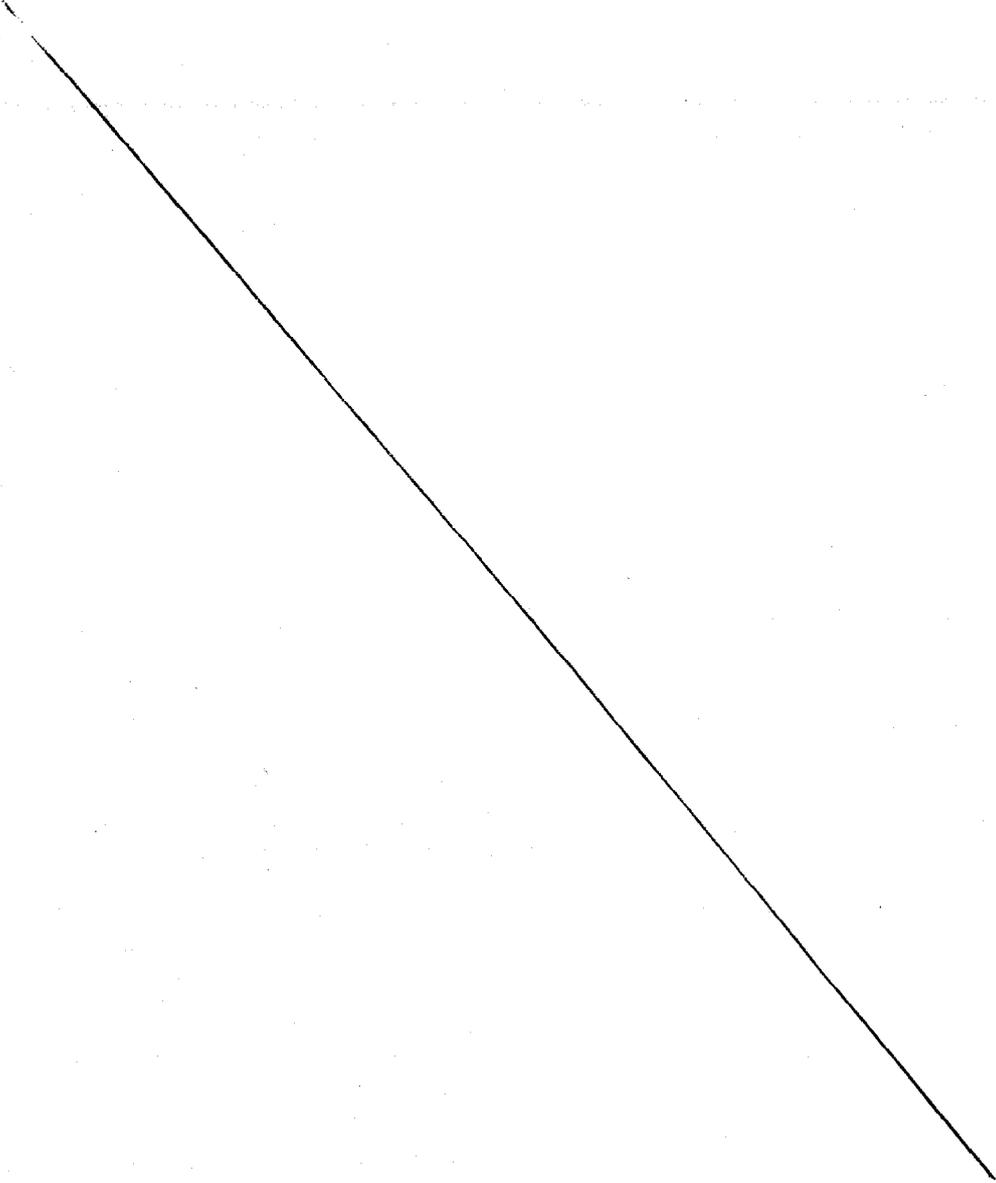
Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.846 is amended by adding paragraph (c)(9) to read as follows:

§ 172.846 Sodium stearoyl lactylate

* * * * *

(c) * * *



(9) As an emulsifier, stabilizer, or texturizer in cream liqueur drinks, at a level not to exceed 0.5 percent by weight of the finished product.

Dated: 10-2-00
October 2, 2000

L. Robert Lake

L. Robert Lake,
Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Stephen N. Reese