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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 97F-0157]

Indirect Food Additives: Polymers

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 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774-25-9) as a fluid absorbent material intended for use in contact with food. This action responds to a petition filed by Japan Vilene Co., Ltd.

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: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 22, 1997 (62 FR 19580), FDA announced that a food additive petition (FAP 7B4537) had been filed by Japan Vilene Co., Ltd., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191

(current 5200 Wolf Run Shoals Rd., Woodbridge, VA 22192). The petition proposed to amend the food additive regulations to provide for the safe use of 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774-25-9) as a fluid absorbent material intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in 21 CFR 177.1211 should be amended as set forth below in this document.

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.

The agency has carefully considered the potential environmental effects of this action. FDA 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 final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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 177

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 Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

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

2. Section 177.1211 is amended by revising paragraphs (a), (d), and the last sentence in paragraph (c) to read as follows:

§ 177.1211 Cross-linked polyacrylate copolymers.

* * * * *

(a) *Identity.* For the purpose of this section, the cross-linked polyacrylate copolymers consist of:

(1) The grafted copolymer of cross-linked sodium polyacrylate identified as 2-propenoic acid, polymers with *N,N*-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft (CAS Reg. No. 166164-74-5); or

(2) 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774-25-9).

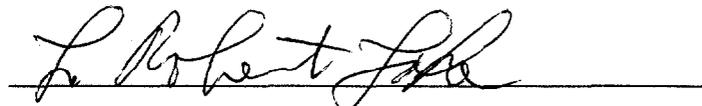
* * * * *

(c) *Extractive limitations.* * * * The solvent used shall be at least 60 milliliters aqueous sodium chloride solution per gram of copolymer.

(d) *Conditions of use.* The copolymers identified in paragraph (a)(1) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated

poultry. The copolymers identified in paragraph (a)(2) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated meat and poultry.

Dated: 3/20/00
March 20, 2000



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

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