

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DWB

Display Date	5-24-79
Publication Date	5-25
Certifier	G. W. M. D. B.

21 CFR Part 177

[Docket No. 92F-0368]

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 a grafted copolymer of cross-linked sodium polyacrylate with polyvinyl alcohol for use as a fluid absorbent in food-contact material. This action responds to a petition filed by Stockhausen, Inc.

DATES: The regulation is effective (*insert date of publication in the Federal Register*); 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: Hortense S. Macon, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-206), 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 28, 1992 (57 FR 48803), FDA announced that a food additive petition (FAP 2B4323) had been filed by Stockhausen, Inc., 2408 Doyle St., Greensboro, NC 27406. The petition proposed to amend the food additive regulations to provide for the safe use of cross-linked sodium polyacrylate and/

or a grafted copolymer of cross-linked sodium polyacrylate with vinyl alcohol for use as a fluid absorbent in food-contact material.

The original petition sought approval of several formulations of the additive and the use of the additive as a fluid absorbent in food-contact materials used in the packaging of fruit, meat, poultry, and vegetables. In a subsequent submission to the agency, the petitioner requested that approval of the additive be limited to its use as a fluid absorbent in food-contact materials used in the packaging of poultry. The petitioner also amended its request to seek approval for only the grafted copolymer of cross-linked sodium polyacrylate. In addition, the petitioner provided a more detailed description of the manufacturing of the additive copolymer, which also provided a more accurate name for the additive, “grafted copolymer of cross-linked sodium polyacrylate with polyvinyl alcohol.” Therefore, this regulation is limited to the grafted copolymer of cross-linked sodium polyacrylate intended for use as a fluid absorbent in food-contact materials used in the packaging of poultry.

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 can achieve its intended technical effect, and therefore, (3) the regulations in 21 CFR part 177 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 collection 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 on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objections thereto. 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 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 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 added to subpart B to read as follows:

§ 177.1211 Cross-linked polyacrylate copolymers.

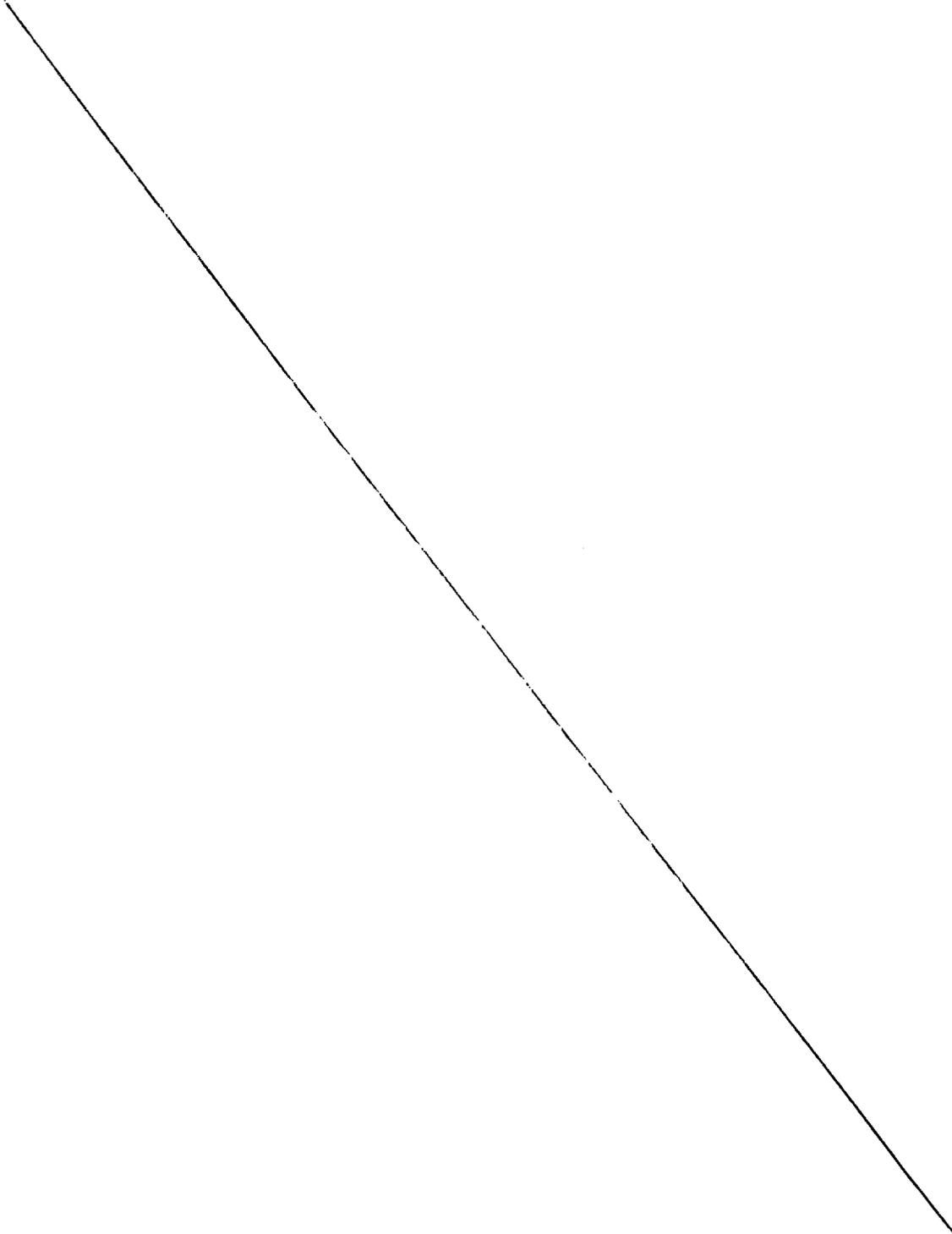
Cross-linked polyacrylate copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions:

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

(b) *Adjuvants.* The copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such copolymers. The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Extractives limitations.* The copolymers identified in paragraph (a) of this section, in the finished form in which they will contact food, must yield low molecular weight (less than 1,000 Daltons) extractives of no more than 0.15 percent by weight of the total polymer when extracted with 0.2 percent by weight of aqueous sodium chloride solution at 20 °C for 24 hours. The low molecular weight extractives shall be determined using size exclusion chromatography or an equivalent method. When conducting the extraction test, the copolymer, with no other absorptive media, shall be confined either in a finished absorbent pad or in any suitable flexible porous article, (such as a “tea bag” or infuser), under an applied pressure of 0.15 pounds per square inch (for

example, a 4x6 inch square pad is subjected to a 1.6 kilograms applied mass). The solvent used shall be 60 milliliters aqueous sodium chloride solution per gram of copolymer.



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

Dated: 5/17/99
May 17, 1999

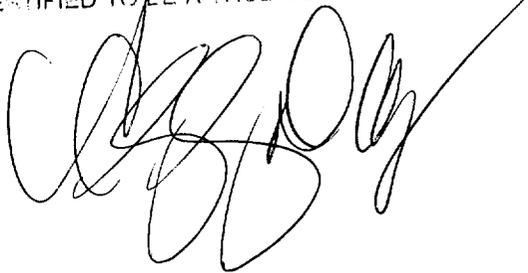
L. Robert Lake

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be 'C. B. O. G.', is written over the certification text.