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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 94F-0246]

**Indirect Food Additives: Polymers**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-vinyl acetate-vinyl alcohol copolymers with revised specifications that provide for a decreased minimum acceptable ethylene content and an increased maximum permitted level of migration of ethylene-vinyl acetate-vinyl alcohol oligomers for use as articles or components of articles intended for contact with food. This action responds to a petition filed by Kuraray 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*]. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 177.1360(d), as of [*insert 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:** Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of August 17, 1994 (59 FR 42277), FDA announced that a food additive petition (FAP 4B4421) had been filed by Kuraray Co., Ltd., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend § 177.1360 *Ethylene-vinyl acetate-vinyl alcohol copolymers* (21 CFR 177.1360) of the food additive regulations to provide for the safe use of ethylene-vinyl acetate-vinyl alcohol copolymers with revised specifications that provide for a decreased minimum acceptable ethylene content and an increased maximum permitted level of migration of ethylene-vinyl acetate-vinyl alcohol oligomers for use as articles or components of articles intended for 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 (3) the regulations in § 177.1360 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.

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, Incorporation by reference.

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 177.1360 is amended by revising paragraphs (a)(3) and (d) to read as follows:

**§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.**

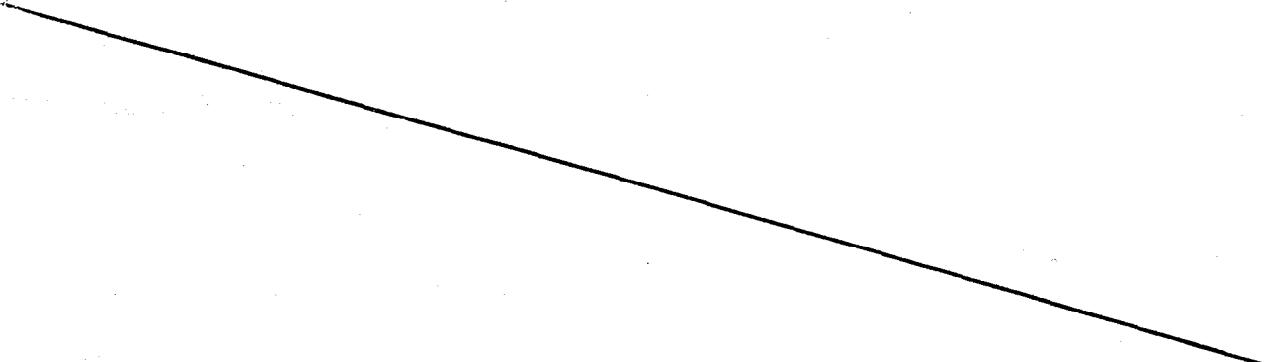
\* \* \* \* \*

(a) \* \* \*

(3) Those copolymers containing 17 to 40 percent ethylene and 60 to 83 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (d) of this section.

\* \* \* \* \*

(d) The finished food-contact article shall not exceed 0.018 centimeter (0.007 inch) thickness and may contact all foods, except those containing more than 8 percent alcohol, under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. Film samples of 0.018 centimeter (0.007 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Methods for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with distilled water at 100 °C (212 °F) for 30 minutes yields ethylene-vinyl acetate-vinyl alcohol oligomers not to exceed 0.093 milligram per square centimeter (0.6 milligram per square inch) of food contact surface as determined by a method entitled "Analytical Method of Determining the Amount of EVOH in the Extractives Residue of EVOH Film," dated March 23, 1987, as developed by the Kuraray Co., Ltd., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW.,



Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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Dated: 3/20/00  
March 20, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

*Jen Windsor*

*L. Robert Lake*

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

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