4100-01

Do ts Management Branch
5600 Fishers Lane
Rockville, Maryland 20857
Rm. 4-62
(HFA-305)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 177

[DOCKET NO. 80F-0312]

DUPLICATE OF THE ORIGINAL
48FR 38604
8-25-83

INDIRECT FOOD ADDITIVES; POLYMERS

9-26-83

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of vinylidene chloride/methyl acrylate copolymers as articles or components of articles in contact with food. This action responds to a petition filed by Dow Chemical Co.

DATES: Effective (insert date of publication in the FEDERAL REGISTER); objections by (insert date 30 days after date of publication in the FEDERAL REGISTER). The Director of the FEDERAL REGISTER approves the incorporation by reference of certain publications at 21 CFR 177.1990, effective on (insert date of publication in the FEDERAL REGISTER).

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

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FOR FURTHER INFORMATION CONTACT:

Mary W. Lipien,
Bureau of Foods (HFF-334),
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204,
202-472-5740.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of September 5, 1980 (45 FR 58968), FDA announced that a petition (FAP 9B3452) had been filed by Dow Chemical Co., 2040 Dow Center, Midland, MI 48640, proposing that the food additive regulations be amended to provide for the safe use of vinylidene chloride/methyl acrylate copolymers as articles or components of articles intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations 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 Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2) 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 (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives; Incorporation by reference; Polymeric food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Foods (21 CFR 5.61), Part 177 is amended in Subpart B by adding new § 177.1990 to read as follows:

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

§ 177.1990 Vinylidene chloride/methyl acrylate copolymers.

The vinylidene chloride/methyl acrylate copolymers (CAS Reg. No. 25038-72-6) identified in paragraph (a) of this section may be safely used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) Identity. For the purposes of this section vinylidene chloride/methyl acrylate copolymers consist of basic copolymers produced by the copolymerization of vinylidene chloride and methyl acrylate such that the copolymers contain not more than 15 weight-percent of polymer units derived from methyl acrylate.

(b) Optional adjuvant substances. The basic vinylidene chloride/methyl acrylate copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These 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) Specifications. (1) The methyl acrylate content is determined by an infrared spectrophotometric method titled "Determination of Copolymer Ratio in Vinylidene Chloride/Methyl Acrylate Copolymers," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The average molecular weight of the copolymer is not less than 50,000 when determined by gel permeation chromatography using tetrahydrofuran as the solvent. The gel permeation chromatograph is calibrated with polystyrene standards. The basic gel permeation chromatographic method is

described in ANSI/ASTM D3536-76, "Standard Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by Liquid Exclusion Chromatography (Gel Permeation Chromatography-GPC)," which is incorporated by reference. Copies are available from University Microfilms International, 300 North Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Residual vinylidene chloride and residual methyl acrylate in the copolymer in the form in which it will contact food (unsupported film, barrier layer, or as a copolymer for blending) will not exceed 10 parts per million and 5 parts per million, respectively, as determined by a gas chromatographic method titled "Determination of Residual Vinylidene Chloride and Methyl Acrylate in Vinylidene Chloride/Methyl Acrylate Copolymer Resins and Films," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) Extractives limitations. The basic copolymer resin in the form of granules that will pass through a U.S. Standard Sieve No. 45 (350 microns) shall meet the following extractives limitations:

(1) 10-gram samples of the resin, when extracted separately with 100 milliliters of distilled water at 157°C (250° F) for 2 hours, and 100 milliliters of n-heptane at 101°C (150° F) for

2 hours, shall yield total nonvolatile extractives not to exceed 0.5 percent by weight of the resin.

(2) The basic copolymer in the form of film when extracted separately with distilled water at 157°C (250° F) for 2 hours shall yield total nonvolatile extractives not to exceed 0.047 milligram per square centimeter (0.3 milligram per square inch).

(e) Conditions of use. The copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, including processing of packaged food at retorting temperature, 157°C (250° F).

(f) Other specifications and limitations. The vinylidene chloride-methyl acrylate copolymers identified in and complying with this section, when used as components of the food contact surface of any article that is subject to a regulation in Parts 174 through 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

Any person who will be adversely affected by the foregoing regulation may at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER) submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection

is made. 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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective (insert date of publication in the FEDERAL REGISTER).

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348).)

Dated: 8/17/83.

AUG 17 1983

Sanford A. Miller
Director, Bureau of Foods

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Marcia Fulayson