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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 177

[Docket No. 99F-0461]

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 polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food. This action is in response to a petition filed by Ticona.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 19, 1999 (64 FR 13586), FDA announced that a food additive petition (FAP 9B4644) had been filed by Ticona, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001.

The petition proposed to amend the food additive regulations in part 177 *Indirect Food Additives:*

Polymers (21 CFR part 177) to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food.

FDA has evaluated the 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) that the regulations in part 177 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4644 (64 FR 13586, March 19, 1999). 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.

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 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 objection 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 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 177.2500 is added to subpart C to read as follows:

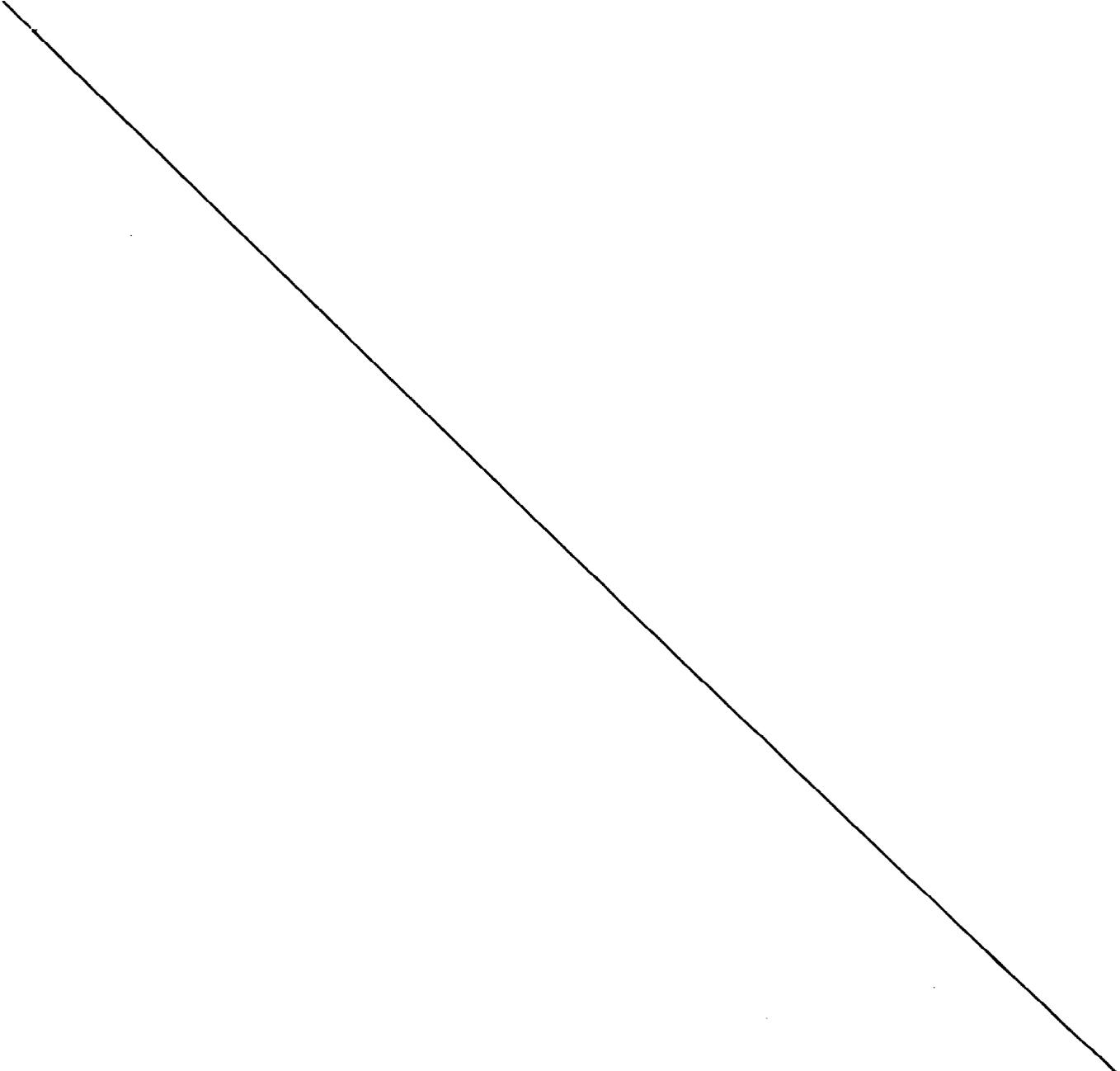
§ 177.2500 Polyphenylene sulfone resins.

The polyphenylene sulfone resins (CAS Reg. No. 31833–61–1) identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, polyphenylene sulfone resins consist of basic resin produced by reacting polyphenylene sulfide with peracetic acid such that the finished resins meet the specifications set forth in paragraph (c) of this section. The polyphenylene sulfide used

to manufacture polyphenylene sulfone is prepared by the reaction of sodium sulfide and *p*-dichlorobenzene, and has a minimum weight average molecular weight of 5,000 Daltons.

(b) *Optional adjuvant substances.* The basic polyphenylene sulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, or substances used in accordance with a prior sanction or approval.



(c) *Specifications.* The glass transition temperature of the polymer is 360 ± 5 °C as determined by the use of differential scanning calorimetry.

Dated: 2/27/00
February 29, 2000

L. Robert Lake

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

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windsor

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