

That despite receiving such notice, the Board may, if it finds the interests of such claimant to be served thereby, recognize actions by, conduct transactions with, and make payments to such claimant.

(c) *Policy used to determine whether to make representative payment.* (1) The Board's policy is that every claimant has the right to manage his or her own benefits. However, due to mental or physical condition some claimants may be unable to do so. If the Board determines that the interests of a claimant would be better served if benefit payments were certified to another person as representative payee, the Board will appoint a representative payee in accordance with the procedures set forth in this part. The Board may appoint a representative payee even if the claimant is a legally competent individual. If the claimant is a legally incompetent individual, the Board may appoint the legal guardian or some other person as a representative payee.

(2) If payment is being made directly to a claimant and a question arises concerning his or her ability to manage or direct the management of benefit payments, the Board may, if the claimant has not been adjudged legally incompetent, continue to pay the claimant until the Board makes a determination about his or her ability to manage or direct the management of benefit payments and the selection of a representative payee.

§ 348.2 Recognition by the Board of a person to act in behalf of another.

The provisions of part 266 of this chapter shall be applicable to the appointment of a representative payee under this part to the same extent and in the same manner as they are applicable to the appointment of a representative payee under the Railroad Retirement Act.

Dated: August 6, 1996.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96-20785 Filed 8-14-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 96F-0053]

Indirect Food Additives: Adhesives and Components of Coatings

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 dimethyl 1,4-cyclohexanedicarboxylate as a monomer in polyester resins employed in adhesives as components of articles intended for use in contact with food. This action is in response to a petition filed by Eastman Chemical Co.

DATES: Effective August 15, 1996; written objections and requests for a hearing by September 16, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), 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 February 26, 1996 (61 FR 7111), FDA announced that a food additive petition (FAP 5B4481) had been filed by Eastman Chemical Co., P.O. Box 1994, Kingsport, TN 37662. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of dimethyl 1,4-cyclohexanedicarboxylate as a monomer in polyester resins employed in adhesives as components of articles intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the food additive is safe, (2) the food additive will have the intended technical effect, and (3) the regulations in § 175.105 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.

Any person who will be adversely affected by this regulation may at any time on or before September 16, 1996, 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 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding a new entry under the heading "Substances" and the subheading "Acids" appearing after the entry for "Polyester resins * * *" to read as follows (for the convenience of the

reader, the introductory text for "Polyester resins" is republished):

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * Polyester resins (including alkyd type), as the basic polymer, formed as esters when one or more of the following acids are made to react with one or more of the following alcohols: Acids:	* * * *
* * * Dimethyl 1,4-cyclohexanedicarboxylate (CAS Reg. No. 94-60-0).	* * * *
* * *	* * * *

Dated: July 29, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

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21 CFR Part 177

[Docket No. 95F-0331]

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 polyaryletherketone resins (i.e., poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylenecarbonyl-1,4-phenylene) as a basic resin for use in food-contact materials. This action is in response to a petition filed by BASF Aktiengesellschaft.

DATES: Effective August 15, 1996; written objections and requests for a hearing by September 16, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), 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 October 19, 1995 (60 FR 54076), FDA announced that a food additive petition (FAP 5B4483) had been filed by BASF Aktiengesellschaft, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations to provide for the safe use of polyaryletherketone resins (i.e., poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylenecarbonyl-1,4-phenylene) as a basic resin for use in food-contact materials, establishing a new food additive regulation, § 177.1556 *Polyaryletherketone resins* (21 CFR 177.1556). Subsequently, the petition was amended to request approval only for the use of the polyaryletherketone resins in repeated use food-contact applications. This amendment is reflected in this final rule.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of residual methylene chloride, which is a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as methylene chloride, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called "general safety clause" of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984).

II. Safety of the Petitioned Use of the Additive

FDA finds that migration of polyaryletherketone resins is unlikely because of the insolubility of the