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.

[FR Doc. 96–20858 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

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-pheneyleneoxy-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

polymer itself. However, the potential dietary concentration of the oligomers migrating from the additive into food would be no greater than 6 parts per billion (ppb), which equates to an estimated daily intake (EDI) of 18 micrograms per person per day (µg/person/day) (Ref. 1). The agency concludes, further, that the total nonvolatile extractives (TNE's) are exclusively oligomers, and therefore, the dietary exposure to the TNE's is also 6 ppb with an EDI of 18 µg/person/day.

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicity data on the additive and concludes that the low exposure to the oligomers and TNE's resulting from the proposed use of the additive is safe.

FDA has evaluated the safety of the additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by methylene chloride, a carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of methylene chloride has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Methylene chloride

FDA has estimated the hypothetical worst-case exposure to methylene chloride from the petitioned use of the additive in repeat use food processing articles to be 8 parts per trillion of the daily diet (3 kilograms), or 20 nanogram (ng)/person/day (Ref. 3). The agency used data in a National Toxicity Program report (No. 306: 1986) on inhalation studies in F344/N rats and $B6C3F_1$ mice (Ref. 4) to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive (Ref. 4). The results of the bioassays demonstrated that the material was carcinogenic in male and female $B6C3F_1$ mice under the conditions of the study. The test material caused an increased incidence of liver cell neoplasms and lung neoplasms in male and female mice.

Based on the estimated worst-case exposure to methylene chloride of 20 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is 1.5×10^{-10}, or 1.5 in 10 trillion (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to methylene chloride is likely to be substantially less than the worst-case exposure, and therefore, the upper-bound lifetime human risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to methylene chloride would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of methylene chloride present as an impurity in the additive. The agency finds that a specification is not necessary for the following reasons: (1) Because of the low level at which methylene chloride may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to this impurity, even under worst-case assumptions, is very low, 1.5 in 10 trillion.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive in repeated use food-contact articles is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, the agency has concluded that a new § 177.1556 *Polyaryletherketone resins* should be established 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.

IV. Environmental Impact

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.

V. Objections

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.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216), concerning FAP 5B4483. Submissions of 2/13/96; BASF Aktiengesellschaft. Exposure to oligomers and total nonvolatile extracts from the use of polyaryletherketone resins in repeat use articles, April 11, 1996.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' *Chemical Safety Regulation and Compliance,* edited by F. Homburger and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. Memorandum from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216), concerning

FAP 5B4483, BASF Aktiengesellschaft, concerning exposure to methylene chloride from the use of polyaryletherketone resins, February 14, 1996.

4. ''Toxicology and Carcinogenesis Studies of Dichloromethane (methylene chloride) (CAS Reg. No. 75–09–2) in F344/N Rats and B6C3F_1 Mice'' (Inhalation Studies). National Toxicology Program Technical Report Series, No. 306 (1986).

5. Memorandum from the Quantitative Risk Assessment Committee, concerning estimation of upper-bound lifetime risk from methylene chloride for uses requested in FAP 5B4483 (BASF Aktiengesellschaft), February 20, 1996.

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

2. New § 177.1556 is added to subpart B to read as follows:

§ 177.1556 Polyaryletherketone resins.

The poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylenecarbonyl-1,4-phenylene) resins (CAS Reg. No. 55088–54–5 and CAS Reg. No. 60015–05–6 and commonly referred to as polyaryletherketone resins) 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.* Polyaryletherketone resins consist of basic resins produced by reacting 4,4′-diphenoxy benzophenone and terephthaloyl dichloride in such a way that the finished resins have a minimum weight average molecular weight of 20,000 grams per mole, as determined by light scattering measurements in sulfuric acid at room temperature.

(b) *Optional adjuvant substances.* The basic polyaryletherketone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These adjuvants may include substances used in accordance with § 174.5 of this chapter and the following:

(1) Benzoyl chloride, poly(tetrafluoro ethylene).

(2) [Reserved]

(c) *Extractive limitations.* The finished food-contact article yields net total extractives in each extracting solvent not to exceed 0.052 milligram per square inch (corresponding to 0.008 milligram per square centimeter) of food-contact surface, when extracted at reflux temperature for 2 hours with the following solvents: Distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid (by weight) in distilled water, and *n*-heptane.

(d) In testing the finished food-contact article made of polyaryletherketone resin, use a separate test sample for each required extracting solvent.

Dated: August 2, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20852 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0385]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of May 21, 1996 (61 FR 25395). The document amended the food additive regulations to provide for the safe use of formaldehyde, polymer with 1-naphthylenol, as a release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: May 21, 1996.

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.

In FR Doc. 96–12761, appearing on page 25395 in the Federal Register of Tuesday, May 21, 1996, the following corrections are made:

1. On page 25395, in the first column, under the ''**SUMMARY**'' caption, in the fifth line, and under the ''**SUPPLEMENTARY INFORMATION**'' caption, in the first paragraph, beginning in the thirteenth line, ''1-naphthylenol'' is corrected to read ''1-naphthalenol''.

§ 178.3860 [Corrected]

2. On page 25396, in the Table, under the heading ''List of substances,'' ''1-naphthylenol'' is corrected to read ''1-naphthalenol''.

Dated: July 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20821 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 179

[Docket No. 94F–0125]

Irradiation in the Production, Processing, and Handling of Food

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 source of high intensity pulsed light to control microorganisms on the surface of food. This action is in response to a food additive petition filed by Foodco Corp. (now known as PurePulse Technologies, Inc.).

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: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of May 2, 1994 (59 FR 22673), FDA announced that a food additive petition (FAP 4M4417) had been filed by Foodco Corp., 8888 Balboa Ave., San Diego, CA 92123, proposing that the food additive regulations be amended to provide for the safe use of a source of high intensity pulsed light to control microorganisms on the surface of food. (Since the publication of the notice of filing, Foodco Corp. has changed its