

21 CFR Part 172**[Docket No. 94F-0223]****Food Additives Permitted for Direct Addition to Food for Human Consumption; Polydextrose****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 polydextrose produced by using phosphoric acid. This action is in response to a petition filed by A. E. Staley Manufacturing Co.

DATES: Effective October 24, 1995; written objections and requests for a hearing by November 24, 1995.

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

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3107.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 15, 1994 (59 FR 36204), FDA announced that a food additive petition (FAP 4A4422) had been filed by A. E. Staley Manufacturing Co., c/o P.O. Box 151, Decatur, IL 62525. The petition proposed to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to provide for the safe use of polydextrose produced using phosphoric acid in place of citric acid.

The petition provided data that demonstrated that polydextrose manufactured using phosphoric acid in place of citric acid is equivalent to polydextrose produced in accordance with § 172.841. FDA further determined that the very low levels of residual phosphate in polydextrose produced using phosphoric acid are both chemically and toxicologically insignificant (Ref. 1). Therefore, based on its evaluation of the data in the petition and other relevant material, FDA concludes that the proposed food additive use is safe, and that the regulation 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 (address above)

by appointment with the information contact person listed above. As provided in 21 CFR 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 November 24, 1995, 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.

Reference

The following reference has 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 M. J. DiNovi, Chemistry Review Branch, CFSAN, to R. M. Angeles, Novel Ingredients Branch, CFSAN, October 7, 1994.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

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 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.841 is amended by revising paragraph (a)(1) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(a)(1) Polydextrose (CAS Reg. No. 68424-04-4) is a partially metabolizable water-soluble polymer prepared by the condensation of a melt which consists either of approximately 89 percent D-glucose, 10 percent sorbitol, and 1 percent citric acid or of approximately 90 percent D-glucose, 10 percent sorbitol, and 0.1 percent phosphoric acid, on a weight basis.

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Dated: October 17, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-26358 Filed 10-23-95; 8:45 am]

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21 CFR Part 177**[Docket No. 91F-0371]****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 ultra-filtration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer for processing foods. This action is in response to a petition filed by Keller and Heckman.

DATES: Effective October 24, 1995; written objections and requests for a hearing by November 24, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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 15, 1991 (56 FR 51719), FDA announced that a food additive petition (FAP 1B4287) had been filed by Keller and Heckman, 1001 G St. NW., suite 500 West (formerly, 1150 17th St. NW.), Washington, DC 20001. The petition proposed that the food additive regulations be amended in § 177.2910 *Ultra-filtration membranes* (21 CFR 177.2910) to provide for the safe use of ultra-filtration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer for processing foods.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that § 177.2910 should be amended as set forth below.

Information in the petition indicates that one of the components of the surface modifier for the ultra-filtration membrane, tetraethylene glycol diacrylate (TEGDA), may be a weak rodent carcinogen when applied to the skin (Ref. 1). FDA evaluated this study and has concluded that the evidence that TEGDA may be a weak dermal carcinogen in rodents does not preclude a conclusion that the petitioned use of the food additive is safe.

First, in the dermal rodent study, there was evidence of systemic exposure to the test compound and an assessment of TEGDA's ability to induce tumors at sites distant from the dermal application. The study reported that an examination of several sentinel tissues, including heart, lung, spleen, kidney, bladder, thyroid, adrenal, testes, prostate, and stomach provided no evidence that TEGDA causes tumors systemically. Second, dermal carcinogenicity is not highly predictive of carcinogenicity by other routes of exposure (Ref. 2). These observations support the agency's view that there is no evidence that suggests that TEGDA is likely to be a carcinogen when orally

ingested, which is the route of exposure most directly relevant to the safety assessment of food additives.

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 21 CFR 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 November 24, 1995, 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.

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. Barkley, W., and L. Klaus Stemman, "Chronic Mouse Dermal Toxicity Study," revised May 1986, submitted to Keith A. Bearson by Department of Environmental Health, University of Cincinnati Medical Center, Cincinnati, OH, (unpublished), submitted in Food Additive Petition No. 1B4287, p. 430, 1991.

2. Tobin, Paul S. et al., "An Evaluation of Skin Painting Studies as Determinants of Tumorigenesis Potential Following Skin Contact With Carcinogens," *Regulatory Toxicology and Pharmacology*, vol. 2, 22-37, 1982.

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. Section 177.2910 is amended by revising the introductory text, by adding new paragraph (a)(4), by redesignating paragraphs (e) and (f) as paragraphs (f) and (g), and by adding a new paragraph (e) to read as follows:

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section may be safely used in the processing of food, under the following prescribed conditions;

(a) * * *

(4) Ultrafiltration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer.

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(e) Ultrafiltration membranes identified in paragraph (a)(4) may be used to filter aqueous or acidic foods containing up to 13 percent of alcohol at temperatures not to exceed 21°C (70°F).

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Dated: October 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-26268 Filed 10-23-95; 8:45 am]

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