

216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 12, 1996 (61 FR 65405), FDA announced that a food additive petition (FAP 7B4528) had been filed by Elf Atochem North America, Inc., 2000 Market St., Philadelphia, PA 19103-3222. The petition proposed to amend the food additive regulations in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) to provide for the safe use of polyamide/polyether block copolymers prepared by reacting a copolymer of *omega*-laurolactam and adipic acid with poly(tetramethylene ether glycol) for use in the manufacture of rubber articles intended for repeated use in contact with food.

FDA has evaluated 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 that therefore, (3) the regulations in § 177.2600 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 March 23, 1998, 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 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, 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.2600 is amended in paragraph (c)(4)(i) by alphabetically adding a new entry to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

* * * * *

(c) * * *

(4) * * *

(i) * * *

Polyamide/polyether block copolymers (CAS Reg. No. 77402-38-1 prepared by reacting a copolymer of *omega*-laurolactam and adipic acid with poly(tetramethylene ether glycol). The polyamide and polyether components are reacted in ratios such that the polyamide component constitutes a minimum of 30 weight-percent of total polymer units. The copolymers may be used in contact with foods of Types I, II, III, IV, V, VI, VII, VIII, and IX identified in Table 1 of § 176.170(c) of this chapter at temperatures not to exceed 150 °F except that those copolymers prepared with less than 50 weight-percent of polyamide are limited to use in contact with such foods at temperatures not to exceed 100 °F.

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Dated: February 6, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-4310 Filed 2-19-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 96F-0410]

Food Additives Permitted in Feed and Drinking Water of Animals; Sodium Stearate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additives regulations to provide for the safe use of sodium stearate as an anticaking agent in animal feeds. This action is in response to a food additive petition (animal use) filed by Betty J. Pendleton, Chesterfield, MO.

DATES: Effective February 20, 1998; written objections and requests for a hearing by March 23, 1998.

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

FOR FURTHER INFORMATION CONTACT: John P. Honstead, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1728.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 6, 1996 (61 FR 64754), FDA announced that a food additive petition (animal use) (FAP 2236) had been filed by Betty J. Pendleton, 15505 Country Ridge Dr., Chesterfield, MO 63017. The petition proposed that the regulations in § 573.280 *Feed-grade calcium stearate* (21 CFR 573.280) be amended to provide for the safe use of sodium stearate as an anticaking agent in animal feeds. The notice of filing provided for a 60-day comment period. No comments have been received.

FDA has evaluated data in the petition and other relevant material. FDA concludes that the proposed food additive use of sodium stearate as an

anticaking agent for animal feeds is safe when used in accordance with current good manufacturing practices.

In accordance with § 571.1(h) (21 CFR 571.1(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 Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(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 March 23, 1998, 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 573

Animal feeds, Food additives.
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 Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.280 is revised to read as follows:

§ 573.280 Feed-grade calcium stearate and sodium stearate.

Feed-grade calcium stearate and sodium stearate may be safely used in an animal feed in accordance with the following prescribed conditions:

(a) Feed-grade calcium stearate and sodium stearate are the calcium or sodium salts of a fatty acid mixture that is predominately stearic acid. Associated fatty acids, including palmitic acid and minor amounts of lauric, myristic, pentadecanoic, margaric, arachidic, and other fatty acids may be contained in the mixture, but such associated fatty acids in aggregate do not exceed 35 percent by weight of the mixture. The fatty acids may be derived from feed-grade fats or oils.

(b) The additives meet the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) They are free of chick-edema factor.

(c) The additives are manufactured so that in aqueous solution they are exposed for 1 hour or longer to temperature in excess of 180 °F.

(d) They are used as anticaking agents in animal feeds in accordance with current good manufacturing practices.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-4223 Filed 2-19-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI58-01-7266; FRL-5967-3]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rulemaking finalizes the United States Environmental Protection Agency's (USEPA) disapproval of the State Implementation Plan (SIP) revision submitted by Michigan containing start-up, shutdown and malfunction (SSM) regulations which would apply generally to sources covered under the applicable SIP. This action is being taken under section 110 of the Clean Air Act (Act).

DATES: This final rule is effective March 23, 1998.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Kathleen D'Agostino at (312) 886-1767 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 886-1767.

SUPPLEMENTARY INFORMATION:

I. Background

On March 20, 1997 (62 FR 13357), the USEPA published a document proposing disapproval of a SIP revision containing Rules 336.1912, 336.1913 and 336.1914, which was submitted by the Michigan Department of Environmental Quality (MDEQ) on May 16 1996. Rule 336.1912 requires that a source be operated in a manner consistent with good air pollution control practices for minimizing emissions during start-ups, shutdowns and malfunctions, and contains notice and reporting requirements in the event of start-up, shutdown or malfunction. Rules 336.1913 and 336.1914 excuse excess emissions resulting from start-ups, shutdowns or malfunctions, providing that the notice and reporting requirements in Rule 336.1912 are met. The rationale for USEPA's proposed action is explained in the notice of proposed rulemaking and will not be restated here.

II. Public Comments/Response to Comments

This section summarizes the comments submitted during the public comment period for the notice of proposed rulemaking and provides USEPA's response to those comments. The comment period closed April 21, 1997. Adverse comments were received from the Michigan Department of