DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 98F–0749]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Ion Exchange Resins

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 the ion exchange resin, methylacrylate-divinyl benzene diethylene glycol divinyl ether terpolymer containing not less than 3.5 percent by weight of divinyl benzene and not more than 0.6 percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine (DMAPA) to treat water and aqueous foods without limits on the conditions of use, and with a specification for DMAPA, an impurity in the ion exchange resin. This action is in response to a petition filed by Rohm and Haas Co.

DATES: This regulation is effective (*insert date of publication in the* **Federal Register**); written objections and requests for a hearing by (*insert date 30 days after date of publication in the* **Federal Register**). The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in § 173.25(b)(2) (21 CFR 173.25(b)(2)), effective (*insert 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: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 15, 1998 (63 FR 49360), FDA announced that a food additive petition (FAP 8A4609) had been filed by Rohm and Haas Co., 100 Independence Mall West, Philadelphia, PA 19106–2399. The petition proposed to amend the food additive regulations in § 173.25 *Ion exchange resins* to provide for the safe use of the ion exchange resin, methylacrylate-divinyl benzene diethylene glycol divinyl ether terpolymer, identified in § 173.25(a)(16), to treat water and aqueous foods as described in § 173.25(b)(2), without limits on the conditions of use, and with a specification for DMAPA, an impurity in the ion exchange resin.

The ion exchange resin is currently approved in § 173.25(a)(16) and (b)(2) as an ion exchange resin used to treat water and aqueous food only of the types identified under categories I, II, and VI–B in Table 1 of § 176.170(c), provided that the temperature of the water or food passing through the resin bed is maintained at 50 °C or less and the flow rate of the water or food passing through the beds is not less than 0.5 gallon per cubic foot per minute. Rohm and Haas Co. has requested that the regulation in § 173.25(b)(2) be amended to provide for use of the ion exchange resin bed without the restrictions on temperature and flow rate, but with establishment of a specification of no more than 1 milligram (mg)/kilogram of DMAPA when extracted into a food-simulating solvent and when measured by the method that is incorporated by reference.

FDA estimates that the petitioned use of the ion exchange resin will result in an estimated daily intake for DMAPA of 0.2 mg per person per day (p/d) for the 90th percentile consumer, assuming that all foods will be processed with this resin. This exposure is well below the acceptable daily intake of 30 mg/p/d established by toxicology studies submitted with the previous petitions for this resin.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the ion exchange resin, methylacrylate-divinyl benzene diethylene glycol divinyl ether terpolymer containing not less than 3.5 percent by weight of divinyl benzene and not more than 0.6 percent by weight of diethylene glycol divinyl ether, aminolyzed with DMAPA, to treat water and aqueous foods without limits on the conditions of use, and with a specification for DMAPA, an impurity in the ion exchange resin, is safe, the ion exchange resin will achieve its intended effect, and therefore, that the regulations in § 173.25 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 8A4609 (63 FR 49360). 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 collections 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 on or before (*insert date 30 days after date of publication in the* **Federal Register**), 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 173

Food additives, Incorporation by reference.

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 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

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

2. Section 173.25 is amended by adding paragraphs (b)(2)(i) and (b)(2)(ii) to read as follows:

§ 173.25 Ion-exchange resins.

* * * * *

(b) * * *

(2) * * *

(i) The ion-exchange resin identified in paragraph (a)(13) of this section is used to treat water and aqueous food only of the types identified under categories I, II, and VI–B in Table 1 of

§ 176.170(c) of this chapter: *Provided*, That the temperature of the water or food passing through the resin bed is maintained at 50 °C or less and the flow rate of the water or food passing through the bed is not less than 0.5 gallon per cubic foot per minute.

(ii) The ion-exchange resin identified in paragraph (a)(16) of this section is used to treat water and aqueous food only of the types identified under categories I, II, and VI–B in Table 1 of § 176.170(c) of this chapter, *Provided*, that either:

(A) The temperature of the water or food passing through the resin bed is maintained at 50 °C or less and the flow rate of the water or food passing through the bed is not less than 0.5 gallon per cubic foot per minute; or

(B) Extracts of the resin will be found to contain no more than 1 milligram/kilogram dimethylaminopropylamine in each of the food simulants, distilled water and 10 percent ethanol, when, following washing and pretreatment of the resin in accordance with § 173.25(c)(1), the resin is subjected to the following test under conditions simulating the actual temperature and flow rate of use: ''The Determination of 3-Dimethylaminopropylamine in Food Simulating Extracts of Ion Exchange Resins,'' February 4, 1998, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington,

DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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LOC/OFR

Dated: 9/28/99

September 28, 1999

L. Robert Lake

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

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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