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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 173

[Docket No. 00F-0786]

Secondary Direct Food Additives Permitted in Food for Human Consumption

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 chlorine dioxide produced by treating an aqueous solution of sodium chlorite with hydrogen peroxide in the presence of sulfuric acid. This action is in response to a petition filed by Eka Chemicals, Inc.

DATES: This rule is effective *[insert date of publication in the Federal Register]*. Submit written objections and requests for a hearing by *[insert date 30 days after 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: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 2, 2000 (65 FR 11319), FDA announced that a food additive petition (FAP 0A4716) had been filed by Eka Chemicals, Inc., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 173.300 *Chlorine*

dioxide (21 CFR 173.300) to provide for the safe use of chlorine dioxide produced by treating an aqueous solution of sodium chlorite with hydrogen peroxide in the presence of sulfuric acid.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 173.300 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.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

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.

This final rule contains no collection 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 file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. 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 are to be submitted and are to 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.

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.

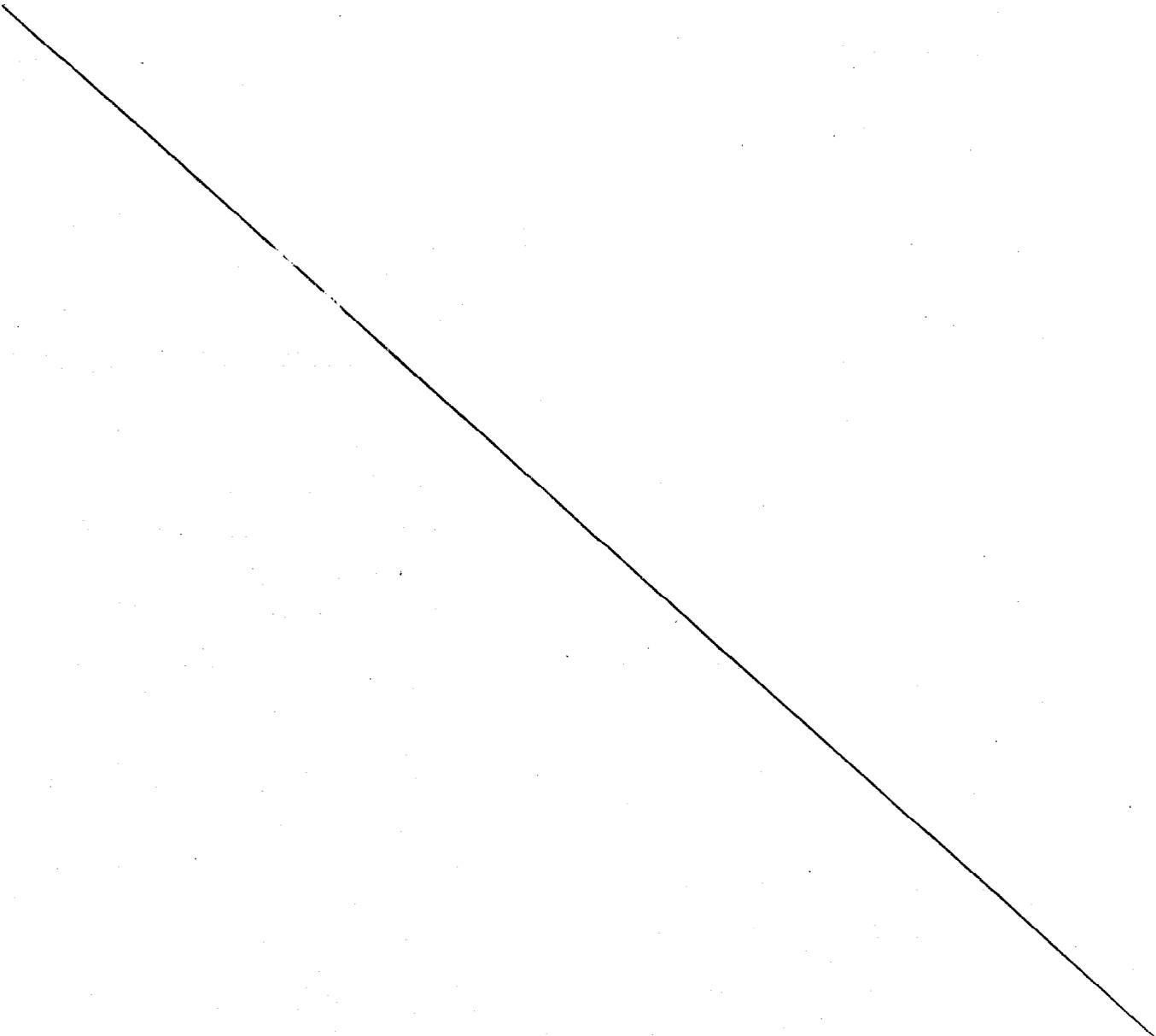
2. Section 173.300 is amended by revising paragraph (a) to read as follows:

§ 173.300 Chlorine dioxide.

* * * * *

(a) The additive is generated by one of the following methods: Treating an aqueous solution of sodium chlorite with either chlorine gas or a mixture of sodium hypochlorite and hydrochloric

acid, or treating an aqueous solution of sodium chlorate with hydrogen peroxide in the presence of sulfuric acid. In either case, the generator effluent contains at least 90 percent (by weight) of chlorine dioxide with respect to all chlorine species as determined by Method 4500-ClO₂ E in the "Standard Methods for the Examination of Water and Wastewater," 18th ed., 1992, or an equivalent method. Method 4500-ClO₂ E is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, and the American Public Health Association, 1015 Fifteenth St. NW., Washington, DC



20005, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW.,
suite 700, Washington, DC.

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Dated: 5/19/00
May 19, 2000



L. Robert Lake
Director of Regulations and Policy
Center for Food Safety and Applied Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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