

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

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[Docket No. 2003F-0535]

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 permit the manufacture of chlorine dioxide by electrolysis of an aqueous solution of sodium chlorite. This action is in response to a petition filed by Vulcan Chemicals.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. See section VI of this document for information on the filing of objections. 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 certain publications in § 173.300 (21 CFR 173.300) as of [*insert date of publication in the Federal Register*].

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2003F-0535, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2003F-0535 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1302.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 1, 2003 (68 FR 67195), FDA announced that a food additive petition (FAP 4A4751) had been

filed by Vulcan Chemicals, P.O. Box 385015, Birmingham, AL 35238–5015. The petition proposed to amend the food additive regulations in § 173.300 *Chlorine dioxide* (21 CFR 173.300) to provide for an additional method for producing the additive, specifically, treating an aqueous solution of sodium chlorite by electrolysis.

In the notice of filing, the agency announced that it was placing the environmental assessment on display at the Division of Dockets Management for public review and comment. FDA did not receive any comments addressing the potential environmental effects of the proposed change to the regulation. As discussed below, the agency has determined that this action will not have a significant impact on the human environment and that an environmental impact statement is not required.

II. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that chlorine dioxide generated by electrolysis of an aqueous solution of sodium chlorite is equivalent to the chlorine dioxide generated by the currently-approved methods as described in § 173.300 (Ref. 1). In addition, the chlorine dioxide generated by the electrolytic process will have the same intended technical effect and use as the chlorine dioxide produced by the currently-approved methods. Consequently, there will be no change in the exposure to chlorine dioxide from the petitioned use. Therefore, FDA concludes that § 173.300 should be amended as set forth below.

Based on a request by the petitioner, the FDA is also updating § 173.300 by citing the 20th edition of the method that is incorporated by reference rather than the 18th edition. Section 173.300 currently incorporates by reference

Method 4500–ClO₂ E in the “Standard Methods for the Examination of Water and Wastewater,” 18th ed., 1992. The agency compared the 18th and 20th editions of this method and found them to be identical. Therefore, the agency is making this requested editorial change.

III. Public Disclosure

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 in this document. 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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Paperwork Reduction Act of 1995

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.

VI. Objection and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written objections by (see

DATES). 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from H. Lee, FDA Division of Petition Review, Chemistry Review Group, to P. DeLeo, FDA, Division of Petition Review, Regulatory Group I, March 17, 2004.

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 173.300 is amended by revising paragraphs (a) and (b) to read as follows:

§ 173.300 Chlorine dioxide.

* * * * *

(a)(1) The additive is generated by one of the following methods:

(i) Treating an aqueous solution of sodium chlorite with either chlorine gas or a mixture of sodium hypochlorite and hydrochloric acid.

(ii) Treating an aqueous solution of sodium chlorate with hydrogen peroxide in the presence of sulfuric acid.

(iii) Treating an aqueous solution of sodium chlorite by electrolysis.

(2) 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,” 20th ed., 1998, or an equivalent method. Method 4500–ClO₂ E (“Amperometric Method II”) is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or the American Public Health Association, 800 I St. NW., Washington, DC 20001–

3750. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b)(1) The additive may be used as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 parts per million (ppm) residual chlorine dioxide as determined by Method 4500-ClO₂ E, referenced in paragraph (a)(2) of this section, or an equivalent method.

(2) The additive may be used as an antimicrobial agent in water used to wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO₂ E, referenced in paragraph (a)(2) of this section, or an equivalent method. Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning.

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Dated: Jan. 28 2005

January 28, 2005.

Leslye M. Fraser

Leslye M. Fraser,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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