

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 99F-0299]

**Secondary Direct Food Additives Permitted in Food for Human Consumption**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on raw agricultural commodities (RAC's). This action is in response to a petition filed by Alcide Corp.

**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 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 3, 1999 (64 FR 10302), FDA announced that a food additive petition (FAP 9A4648) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the

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food additive regulation in § 173.325 to provide for the safe use of aqueous solutions of acidified sodium chlorite as an antimicrobial agent on RAC's.

The petitioner is proposing to limit the use of this additive to RAC's in preparing, packing, or holding of such commodities for commercial purposes, consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(q)(1)(B)(i)), as amended by the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324). The petitioner is not proposing that the additive be intended for use for any application under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, which use would be subject to regulation by the Environmental Protection Agency (EPA) as a pesticide chemical. The proposed use of the additive is to reduce the microbial contamination on RAC's. Under ARTCA, the use of acidified sodium chlorite solutions as an antimicrobial agent on RAC's in preparing, packing, or holding of such RAC's for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not otherwise included within the definition of “pesticide chemical” under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III), is subject to regulation by FDA as a food additive.

Although this use of acidified sodium chlorite solutions as an antimicrobial agent on raw agricultural commodities is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, the intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified sodium chlorite solutions for such use should contact the EPA to determine whether this use requires a pesticide registration under FIFRA.

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 § 173.325 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 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 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.

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 173.325 is amended by redesignating paragraph (e) as paragraph (f) and by adding new paragraph (e) to read as follows:

**§ 173.325 Acidified sodium chlorite solutions.**

\* \* \* \* \*

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities

with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

\* \* \* \* \*

Dated: 9/8/99

September 8, 1999

L Robert Lake

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

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