

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 01F-0233]

DMB
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Certifier R. LEDESMA

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 in water applied to processed fruits and vegetables. This action is in response to a petition filed by Alcide Corp.

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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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 23, 2001 (66 FR 28525), FDA announced that a food additive petition (FAP 1A4729) had been filed by Alcide Corp., 8561 154th Ave., NE., Redmond, WA 98052. The petition proposed to amend the food additive regulations in § 173.325 *Acidified sodium chlorite solution* (21 CFR 173.325) to

provide for the safe use of aqueous solutions of acidified sodium chlorite as an antimicrobial agent in processing waters applied to processed fruits and vegetables.

FDA is using the term “processed” consistent with the meaning of that term set forth in FDA’s Antimicrobial Food Additives—Guidance (64 FR 40612, July 27, 1999) (the 1999 guidance). The 1999 guidance describes FDA’s interpretation of its jurisdiction over antimicrobial substances subsequent to the enactment of the Food Quality Protection Act of 1996 and the Antimicrobial Regulation Technical Corrections Act of 1998. The 1999 guidance is consistent with the Environmental Protection Agency’s (EPA’s) and FDA’s joint legal and policy interpretation of “processed food” (63 FR 54532, October 9, 1998). According to the 1999 guidance, processed fruits and vegetables include those that are ground, chopped, sliced, cut or peeled, and do not include fruits and vegetables that simply have leaves, stems, or husks removed. This food additive use of acidified sodium chlorite is for use in water to which processed fruits and vegetables are added (e.g., to which fruits and vegetables that have been ground, chopped, sliced, cut, or peeled are added) in order to mitigate microbiological organisms on the processed fruits and vegetables.

Also, as discussed in the 1999 guidance, antimicrobial substances used to mitigate microbiological organisms on processed food, by adding such substances to water to which processed food is added, are subject to regulation as food additives. The petitioned use of acidified sodium chlorite as an antimicrobial agent in “processing waters” is intended to mitigate microbiological organisms only on the processed fruits and vegetables that are added to the water. Thus, the petitioned use is subject to regulation by FDA as a food additive. To the extent that a manufacturer wants to use acidified sodium chlorite in water to mitigate microbiological organisms in the water itself or to include mitigation of microbiological organisms in the water in addition to those on the processed fruits and vegetables that are added to the water, the manufacturer would need to petition FDA for that food additive use, which is outside the scope of this rule. In addition, the manufacturer would need to consult with EPA to determine whether a pesticide registration would be required for such use.

FDA is requiring, as part of this regulation, that the use of the additive be followed by a potable water rinse and a 24-hour holding period to ensure that there are no detectable residue levels from the use of the additive on the treated processed fruits and vegetables.

FDA has evaluated the 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 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 considered carefully 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 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 affected adversely by this regulation may 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 numbered separately, and each

numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection for 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 the brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch (address above) 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:

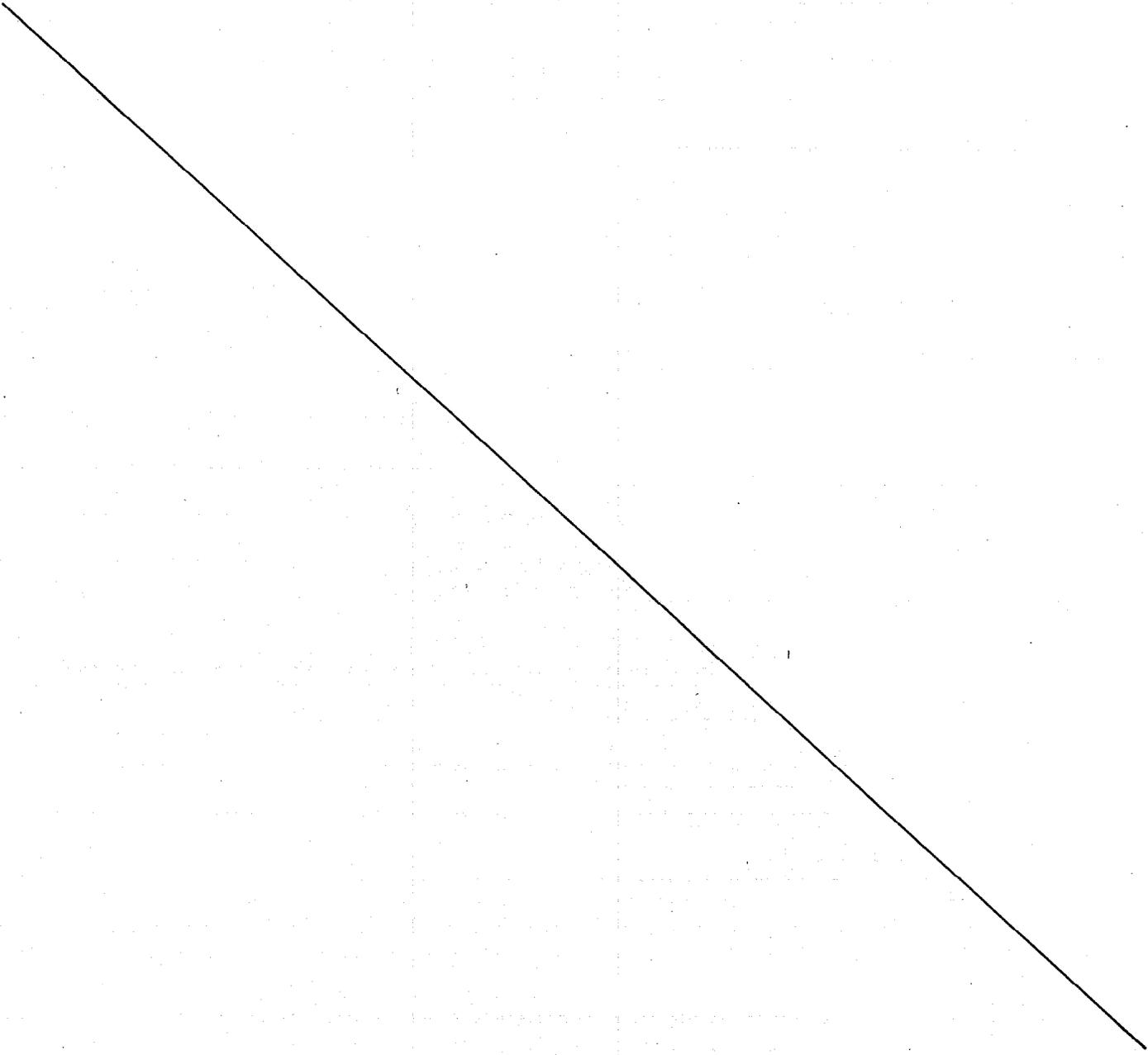
Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (g) as paragraph (h) and by adding new paragraph (g) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, fruiting (i.e., eggplant, groundcherry, pepino, pepper, tomatillo, and tomato), and cucurbit vegetables in accordance with current industry standards of good manufacturing practices, as a component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period prior to consumption. However, for processed leafy vegetables (i.e., vegetables other than root, tuber, bulb, legume, fruiting, and cucurbit vegetables) and vegetables in the Brassica [Cole] family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable



water rinse and a 24-hour holding period prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

* * * * *

Dated: 2/28/02

February 28, 2002.

L. Robert Lake

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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Regina Ledesma