

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Display Date	7-16-99
Publication Date	7-19-99
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Food and Drug Administration

21 CFR Part 173

[Docket No. 98F-0894]

**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 a mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on fruits and vegetables that are not raw agricultural commodities without the requirement of a potable water rinse following treatment. This action is in response to a petition filed by Ecolab, Inc.

**DATES:** This regulation 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:** Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3072.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of October 20, 1998 (63 FR 56035), FDA announced that a food additive petition (FAP 8A4622) had been filed by Ecolab, Inc., 370 North Wabasha St., St. Paul, MN 55102. The petition proposed to amend

the food additive regulation in § 173.315 *Chemicals used in washing or to assist in the peeling of fruits and vegetables* (21 CFR 173.315) to provide for the safe use of a mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent to wash or assist in the lye peeling of fruits and vegetables that are not raw agricultural commodities without the requirement of a potable water rinse following treatment. The use of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid is currently approved under § 173.315 provided its use is followed by a potable water rinse (§ 173.315(c)).

The current approval under § 173.315 for the use of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid is to control the microbial growth in water that contacts fruits and vegetables that are not raw agricultural commodities (61 FR 46374, September 3, 1996). This intended technical effect is unchanged by this regulation. Under the Antimicrobial Regulation Technical Corrections Act (Public Law 105–324), such use in water that comes into contact with the food in the preparing, packing, or holding of the food for commercial purposes is subject to regulation by FDA as a food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) and is not subject to regulation by the Environmental Protection Agency (EPA) as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). However, this intended use of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to use this food additive for this intended use should contact 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 § 173.315 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 potential environmental effects of this rule as announced in the notice of filing for the petition. 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 the 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.

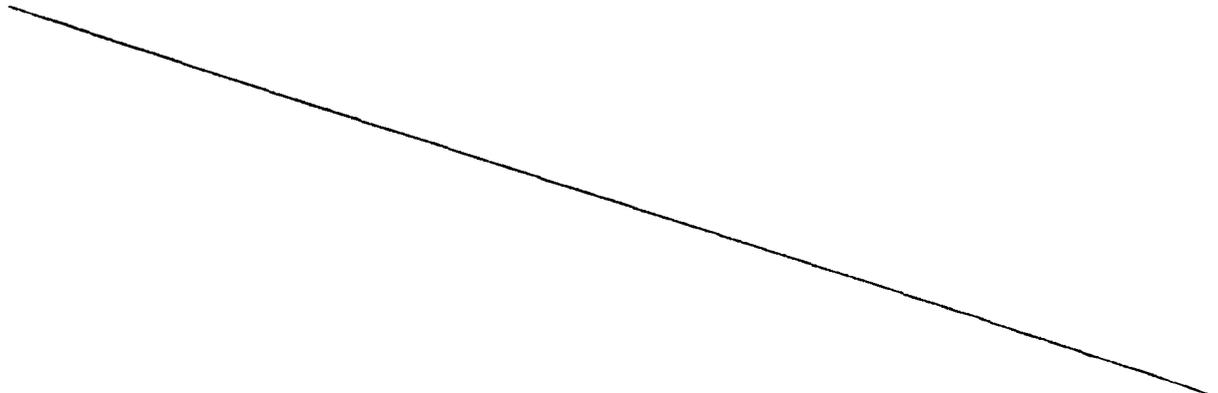
2. Section 173.315 is amended in the table in paragraph (a)(2) by removing the entries for “1-Hydroxyethylidene-1, 1-diphosphonic acid,” “Hydrogen Peroxidé,” and “Peroxyacetic acid”, and by adding paragraph (a)(5) to read as follows:

**§ 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.**

\* \* \* \* \*

(a) \* \* \*

(5) Substances identified in this paragraph (a)(5) for use on fruits and vegetables that are not raw agricultural commodities and subject to the limitations provided:



Substances	Limitations
Hydrogen peroxide .....	Used in combination with acetic acid to form peroxyacetic acid. Not to exceed 59 ppm in wash water.
1-Hydroxyethylidene-1,1-diphosphonic acid .....	May be used only with peroxyacetic acid. Not to exceed 4.8 ppm in wash water.
Peroxyacetic acid .....	Prepared by reacting acetic acid with hydrogen peroxide. Not to exceed 80 ppm in wash water.

\* \* \* \* \*

Dated: July 7, 1999  
July 7, 1999

Janice F. Oliver  
Janice F. Oliver  
Deputy Director  
Center for Food Safety and  
Applied Nutrition

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

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**  
Michael W. Bell