

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 01F-0142]

DMB

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Certifier	<i>R. L. Martin</i>

**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, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on poultry carcasses, poultry parts, and organs. This action is in response to a petition filed by Ecolab, 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*]. 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 a certain publication in § 173.370 as of [*insert 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 30, 2001 (66 FR 17430), FDA announced that a food additive petition (FAP 1A4728) had been filed by

Ecolab, Inc., Ecolab Center, 370 Wabasha St., St. Paul, MN 55102. The petition proposed to amend the food additive regulations in part 173 *Secondary Direct Food Additives Permitted in Food for Human Consumption* (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on poultry carcasses, poultry parts, and organs.

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 and the additive will achieve its intended technical effect as an antimicrobial agent on poultry carcasses, poultry parts, and organs. Therefore, 21 CFR 173.370 is 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 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 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 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 (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### **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 173.370 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 173.370 Peroxyacids.**

\* \* \* \* \*

(b)(1) The additive is used as an antimicrobial agent on red meat carcasses in accordance with current industry practice where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, and the maximum concentration of hydrogen peroxide is 75 ppm.

(2) The additive is used as an antimicrobial agent on poultry carcasses, poultry parts, and organs in accordance with current industry standards of good manufacturing practice (unless precluded by the U.S. Department of Agriculture's standards of identity in 9 CFR part 381, subpart P) where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, the maximum concentration of hydrogen peroxide is 110 ppm, and the maximum concentration of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is 13 ppm.

(c) The concentrations of peroxyacids and hydrogen peroxide in the additive are determined by a method entitled "Hydrogen Peroxide and Peracid (as Peracetic Acid) Content," July 26, 2000, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The concentration of 1-hydroxyethylidene-1,1-diphosphonic acid is determined by a method entitled "Determination of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) Peroxyacid/Peroxide-Containing Solutions," August 21, 2001, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The Director of the Office of the Federal Register approves these incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of these methods from the Division of Petition Review, Center for Food Safety and Applied Nutrition, Food and

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Drug Administration, 200 C St. SW., Washington, DC 20204-0001, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: 9/6/01  
September 6, 2001.

L. Robert Lake

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

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Regina Sedeno