
Memorandum

Date: March 26, 2019

To: E. Furukawa, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Chemist, Division of Food Contact Notifications, HFS-275

Subject: Finding of No Significant Impact for Food Contact Notification 1968 (an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP, CAS Reg. No. 2809-21-4).

Notifier: Ecolab Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1968, which is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1- hydroxyethylidene-1, 1- disphosphonic acid as an antimicrobial agent in spray, wash, rinse, dip, mist, or chill water used during the production and preparation of hard-boiled peeled eggs.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated March 20, 2019, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food contact substance.

Daniel Chan

Attachments:

Finding of No Significant Impact

EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1968, submitted by Ecolab Inc., for the use of an aqueous mixture containing peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), as an antimicrobial agent in spray, wash, rinse, dip, mist, or chill water used during the production and preparation of hard-boiled peeled eggs. The components of the FCS mixture will not exceed: 2000 ppm PAA, 1447 ppm HP, and 85 ppm HEDP.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated March 20, 2019. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as an antimicrobial agent for its intended uses, environmental introduction could occur via wastewater. It is expected that wastewater from an on-site wastewater treatment facility will discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters. Land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in the complete degradation of PAA, HP, and AA. Specifically, the PAA will breakdown into oxygen, and AA, while HP will break down into oxygen and water. Acetic acid dissociates in water to acetate anion and the hydrated proton. Therefore, the EA focuses on the environmental impacts of HEDP.

The use level of 85 ppm for HEDP is the maximum concentration of HEDP that may be expected in a worst-case scenario. HEDP is a chelating agent and exhibits unique partitioning behavior such that 80% adsorbs to wastewater treatment sludge, while the remaining 20% stays in the water. Applying the 80:20 partitioning factors yields an environmental introduction concentration (EIC) in sludge of $85 \text{ ppm} \times 0.8 = 68 \text{ ppm}$. The aquatic EIC is $118 \text{ ppm} \times 0.2 = 17 \text{ ppm}$. In order to arrive at the effective environmental concentration (EEC) in water, a 10-fold dilution factor is applied to the HEDP that remains in water to account for dilution upon release to surface water ($\text{EIC} \div 10 = \text{EEC}$). Therefore, the aquatic EEC is $17 \text{ ppm} \div 10 = 1.7 \text{ ppm}$

HEDP shows no toxicity to terrestrial organisms at levels up to 1,000 mg/kg (ppm) soil dry weight (No Observed Effect Concentration; NOEC), and the lowest relevant endpoint for aquatic toxicity was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Therefore, there is no toxicity expected from land application of sludge containing 68 ppm HEDP. Similarly, discharge to surface waters of effluent containing 1.7 ppm HEDP is not expected to have toxic effects.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (i.e., similar antimicrobial agents already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts, mitigation measures are not identified.

The use of the FCS, as described in FCN 1968, as an antimicrobial agent for use in the processing of the foods described above will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed on 03-26-2019

Daniel Chan

Chemist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed on 03-26-2019

Mariellen Pfeil

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U.S. Food and Drug Administration

Revision Sheet for the March 20, 2019 EA for FCN 1968

Dated: March 25, 2019

U.S. Food and Drug Administration (FDA) in its review of the March 20, 2019 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1968 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to clarify the following:

On page 4 (section 7), the EA states:

“HEDP will mineralize to soil particles and organic matter and utilization of the phosphonate moiety by microorganisms as a phosphorus source.”

This sentence appears to contradict the information in the associated literature citation (footnote 5, reprinted below).

“phosphonates are therefore similar to EDTA, in that little or no biodegradation is observed in natural systems but that microorganisms have been isolated from these environments capable of degrading the compound.”

Nowack, B., Environmental chemistry of phosphonates, Water Research 37(11): 253-2546, June 2003.

To clarify the environmental fate of HEDP in soils, this sentence is revised to:

HEDP will mineralize to soil particles and organic matter. Microorganisms that can utilize the phosphonate moiety as a phosphorus source have been identified in the literature (see footnote 5 of the EA).