

Memorandum

Date: December 4, 2018

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

To: S. Koh-Fallet, 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)

Subject: Finding of No Significant Impact for Food Contact Notification 1936 (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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and, optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9)).

Notifier: Diversey, Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1936, which is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, dipicolinic acid and, optionally, sulfuric acid as an antimicrobial agent in: (1) spray, wash, rinse, dip, chill, and scald water for whole or cut poultry or meat carcasses, parts, trims and organs; and (2) process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated August 24, 2018, 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

Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1936, submitted by Diversey 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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and, optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9) as an antimicrobial agent with intended uses described below. The components of the FCS mixture will not exceed:

1. 2000 ppm PAA, 1474 HP, 118 ppm HEDP, and 0.5 ppm DPA in spray, wash, rinse, dip, chill, and scald water for whole or cut poultry or meat carcasses, parts, trims and organs.
2. 495 ppm PAA, 365 ppm HP, 29 ppm HEDP, and 0.1 ppm DPA in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry.

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 August 24, 2018. 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. Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions and hydrated protons; and is totally miscible in water. Sodium sulfate has a favorable ecological profile. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment. Therefore, the EA focuses on the environmental impacts of HEDP and DPA.

The use level of 118 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 $118 \text{ ppm} \times 0.8 = 94.4 \text{ ppm}$. The aquatic EIC is $118 \text{ ppm} \times 0.2 = 23.6 \text{ ppm}$. 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 $23.6 \text{ ppm} \div 10 = 2.36 \text{ ppm}$

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 94.4 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.36 ppm HEDP is not expected to have toxic effects.

DPA does not exhibit any partitioning behavior; thus, the EEC is assumed to be the maximum use concentration of 0.5 ppm diluted 10-fold to 0.05 ppm. This value is more than 279-fold lower than the lowest predicted DPA toxicity values for freshwater fish (96-hour LC50 is 323.61 mg/L) and green algae (96 hour EC50 is 13.97 mg/L) as determined using the U.S. Environmental Protection Agency ECOSAR (Ecological Structure Activity Relationship) model. Therefore, the effects to aquatic organisms from the intended uses of DPA are expected to be negligible.

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 1936, 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 12-04-2018

Daniel Chan

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Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 12-04-2018

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