Memorandum

Date: December 21, 2017

To: Elizabeth Petro, Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Acting Environmental Team Lead, Office of Food Additive Safety, HFS-255

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1851 for an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (CAS Reg. No. 7664-93-9).

Notifier: Enviro Tech Chemical Services, Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1851, request for use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP), and, optionally, sulfuric acid, as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated November 29, 2017, may be made available to the public. We will post digital transcriptions of the FONSI and the EA 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1851), submitted by Enviro Tech Chemical Services, Inc., to provide for safe use of use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP), and, optionally, sulfuric acid, as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging, as described below.

The Office of Food Additive Safety has determined that allowing this FCN to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement will not be prepared. This finding is based on information submitted by the submitter in an environmental assessment, dated November 29, 2017. The EA is incorporated by reference in this Finding of No Significant Impact, and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms, and will be used in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling throughout the United States.

The components of the FCS mixture will not exceed 4500 ppm PA, 6600 ppm HP, and 180 ppm HEDP. If the FCS mixture is applied at a rate exceeding 0.0175 milliliters treatment solution per ounce container capacity, the FCS mixture must be drained from the container and rinsed with sterile water and drained again. FDA's review of the use of the FCS to sterilize aseptic filling systems is limited to the extent that the FCS residues may transfer from the non-food contact surfaces of the aseptic filling system to food packaging materials.

Waste water from the above-described use will be either discharged ultimately to a publicly-owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment.

The peroxygen components of the FCS (PAA, HP), and the acetic acid are expected to degrade rapidly in the presence of organic material, and sulfuric acid dissociates in the presence of water. Thus, the focus of the environmental analysis is on the stabilizer HEDP. 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. As a worst-case analysis, the proposed use concentration of 180 ppm is assumed to also be the environmental introduction concentrations (EIC). Applying the 80:20 partitioning factors to the EIC yields an effective environmental concentration (EEC) in sludge of 180 ppm x 0.8 = 144 ppm, and an EEC in water of (180 ppm x 0.2) ÷ 10 = 3.6 ppm.

HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (*Eisenia foetida*, 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 144 ppm HEDP. Similarly, discharge to surface waters of effluent containing 3.6 ppm HEDP is not expected to have toxic effects.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents; such action would have no significant environmental impact.

As evaluated in the EA, the use of the FCS as described in FCN 1851 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 12-21-2017
Leah D. Proffitt
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-21-2017
Mariellen Pfeil
Biologist, Acting Environmental Team Lead
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration