

Memorandum

Date: September 23, 2019

To: Vivian Gilliam, Division of Food Contact Substances (HFS-275)

Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact for Food Contact Substance Notification (FCN) 2006 for 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), sulfuric acid (SA) (CAS reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4).

Notifier: DeLaval Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2006 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2006 is for the use of 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), sulfuric acid (SA) (CAS reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) as an antimicrobial agent for the commercial sterilization of aseptic, polymeric food packaging prior to filling.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated August 7, 2019, 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

Food Contact Substance (FCS) Notification (FCN) 1998: FCN 2006, submitted by DeLaval Inc., for the safe use 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), sulfuric acid (SA) (CAS reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) as an antimicrobial agent for the commercial sterilization of aseptic, polymeric food packaging prior to filling, as specified below.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated August 7, 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 and is briefly summarized below.

The FCS may be applied as a spray only in the following applications:

1. The FCS may be applied to polymeric bottles and closures without a rinse prior to filling with food and on the exterior of sealed polymeric food packaging without a rinse. The maximum at-use concentration of PAA, HP, and HEDP may not exceed 508 ppm, 2700 ppm, and 61 ppm, respectively.
2. The FCS may be applied to polymeric containers and closures, drained, and the interior rinsed with potable water. The maximum at-use concentration of PAA, HP, and HEDP may not exceed 2030 ppm, 10,802 ppm, and 244 ppm, respectively.

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) are expected to degrade rapidly in the presence of organic material, and, SA totally dissociates in the presence of water to sulfate ions (SO_4^{2-}) and hydrated protons. As part of the sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate. Also, AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and 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. The EA focuses on the use with the highest HEDP use level (i.e. the second application noted above). Therefore, the HEDP use level of 244 ppm is used to estimate environmental introduction concentrations. Application of the 80:20 sludge:water adsorption factor and 10-fold dilution upon discharge to surface waters yields an EEC of 195.2 ppm for sludge, and 4.9 ppm for water. These concentrations are well below the toxicity endpoints for soil (1000 mg/kg NOEC red worms) and water (10 mg/L NOEC *Daphnia magna*). Therefore, there is no toxicity expected from land application of sludge containing 195.2ppm HEDP. Similarly, discharge to surface waters of effluent containing 4.9 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 2006 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 09-23-2019

Leah D. Proffitt

Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 09-23-2019

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