

Memorandum

Date: February 28, 2020

To: Jessica Urbelis, Ph.D., Division of Food Contact Substances, HFS-275

Through: Antonetta Thompson-Wood, MS, Physical Scientist, 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) 2033 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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) and/or sodium hydroxide (NaOH) (CAS Reg. No. 1310-73-2).

Notifier: Solvay Chemicals, Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2033 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2033 is for the use of an aqueous mixture of PAA, HP, AA, HEDP, and optionally DPA and/or NaOH as an antimicrobial agent in process water and ice used for washing or chilling fruits and vegetables.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated January 20, 2020, 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) 2033: submitted by Solvay Chemicals, Inc., for the safe 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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) and/or sodium hydroxide (NaOH) (CAS Reg. No. 1310-73-2) as an antimicrobial agent in in process water and ice used for washing or chilling fruits and vegetables. The components of the FCS mixture will not exceed 600 ppm PAA, 1112 ppm HP, 934 ppm AA, 34 ppm HEDP, and 0.68 ppm DPA.

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 January 20, 2020. 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 antimicrobial agent is needed to reduce or inhibit the growth of pathogenic and non-pathogenic microorganism that may be present on and in food to provide safer foods for consumers.

Waste water from the above-described uses 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 AA are expected to degrade rapidly in the presence of organic material or after wastewater treatment at the latest (PAA degrades to AA and oxygen while HP breaks down to water and oxygen). Any NaOH toxicity results from possible pH changes; however, these will be managed in accordance with NPDES standards which require that effluent be near neutral before discharge.

Thus, the focus of the environmental analysis is on HEDP and DPA. 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. DPA is water soluble and does not partition to sludge; therefore, it is assumed that the environmental introduction concentration (EIC) is equal to the use concentration (0.68ppm). The DPA aquatic effective environmental concentration (EEC) is 0.068 ppm (i.e. $EIC \div 10$ -fold dilution factor upon release of effluent to surface waters). There is little ecotoxicity information available on DPA itself, so environmental toxicity was assessed using the Environmental Protection Agency's (EPA's) Ecological Structure Activity Relationships (ECOSAR) Class Program, which estimates effects based on structure-activity relationships and predictions from similar chemical classes. The lowest toxicity endpoints, according to ECOSAR, are a chronic value of 29 mg/L for fish (proxy: pyridine-alpha-acid), and a chronic value of 89 mg/L (proxy: neutral organic SAR) for daphnid. The expected worst-case EEC of ≈ 0.07 ppm is almost 3 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.07 ppm DPA is not expected to have toxic effects on aquatic life.

Similarly, the HEDP use level of 34 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 27.2 ppm for sludge, and 0.68 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 27.2 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.68 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 2033 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 02-28-2020

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 03-02-2020

Antonetta Thompson-Wood

Physical Scientist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration