

Memorandum

Date: March 2, 2022

To: Paulina Piotrowski, Ph.D., Division of Food Contact Substances, HFS-275

Through: Mariellen Pfeil, Lead Biologist, Office of Food Additive Safety, HFS-255

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2022.03.03 13:36:39 -05'00'

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

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2210 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-hydroxyethylidine-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: Hydrite Chemical Co.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2210 for use of the above-described FCS an antimicrobial agent used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures 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 December 6, 2021, 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 Digitally signed by Leah D.
Proffitt -S
Date: 2022.03.02 19:50:47
-05'00'
-S
Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt

File: FCN No. 2210

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2210), submitted by Hydrite Chemical Co. to provide 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-hydroxyethylidine-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 used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures 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.

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, dated December 6, 2021. 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 components of the FCS will not exceed 4500 ppm PAA, 6600 ppm HP, 240 ppm HEDP, and 9 ppm DPA when used in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures prior to filling. 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.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in food processing facilities throughout the United States. Wastewater from the proposed 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) 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 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 highest use concentration (9 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.9 ppm (i.e. $\text{EIC} \div 10$ -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 324 ppm 96 hr LC₅₀ for fish (proxy: neutral organic SAR). The expected worst-case EEC of 0.9 ppm is 2-3 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.9 ppm DPA is not expected to have toxic effects on aquatic life.

After accounting for the 80:20 sludge:water adsorption rates for HEDP, the notifier arrives at the following EEC values, and toxicity endpoint comparisons:

EEC_{sludge}: 240 ppm x 0.8 = 192 ppm < 1000 mg/kg NOEC *Eisenia foetida*

EEC_{water}: 240 ppm x 0.2 = 48 ppm ÷ 10 = 4.8 ppm < 10 mg/L NOEC *Daphnia magna*

If applied as a soil amendment, the sludge will be mixed with other soil and its concentration further diluted. The aquatic EEC of 4.8 ppm is an order of magnitude below the range of the most sensitive aquatic toxicity endpoint (10 mg/L NOEC *Daphnia magna*). Therefore, discharge to surface waters of effluent containing 240 ppm HEDP is not expected to have toxic effects.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS as antimicrobial agent alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures 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 will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by  Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S
Date: 2022.03.02 19:51:28
-05'00' Date: see electronic signature

Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by  Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2022.03.03 13:37:06 -05'00' Date: see electronic signature

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration