Memorandum

Date: June 2, 2020

To: Elizabeth Furukawa, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead 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) 2059 for 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), and/or 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 2059 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2059 is for the use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA), and optionally sulfuric acid as an antimicrobial agent used 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 May 12, 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) 2059: submitted by Hydrite Chemical Co., 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), and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9) as an antimicrobial agent 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 (EA) dated May 12, 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 components of the FCS will not exceed 4500 ppm PAA, 2045 ppm HP, 205 ppm HEDP, and 9 ppm DPA in the commercial sterilization of aseptic filling systems and food packaging and their closures prior to filling. The surfaces of food packaging and their closures will be drained, rinsed, and drained again following application of the FCS mixture.

FDA's review of the use of the FCS in 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 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 use concentration (9 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.9 ppm (i.e. EIC ÷ 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). The expected worst-case EEC of 0.9 ppm 2 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.

Similarly, the HEDP use level of 205 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 164 ppm for sludge, and 4.1 ppm for water. The sludge EEC is well below the toxicity endpoint for soil (1000 mg/kg NOEC *Eisenia foetida*). If applied as a soil amendment, the sludge will be mixed with other soil and its concentration further diluted.

The aquatic EIC of 4.1 ppm is an order of magnitude below the range of the most sensitive aquatic toxicity endpoint (10 - 12.5 mg/L NOEC *Daphnia magna*). Therefore, discharge to surface waters of effluent containing 4.1 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 2059 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 06-02-2020
Leah D. Proffitt
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Office of Food Additive Safety
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Approved by _____Date: digitally signed 06-02-2020
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