Memorandum

Date: November 10, 2020

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Notification (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 (FONSI) for Food Contact Substance Notification (FCN) 2096: an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA), and optionally, sulfuric acid.

Notifier: Hydrite Chemical Co.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2096, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2096 is for an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA), and optionally, sulfuric acid.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated October 16, 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.

Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2096, submitted by Hydrite Chemical Co. for: an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA), and optionally, sulfuric acid.

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 (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated October 16, 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 (FONSI) and is briefly summarized below.

The FCS is intended to be used as an antimicrobial agent in the commercial sterilization of aseptic filling systems, as well glass and plastic food packaging and their closures prior to filling. The components of the FCS will not exceed 4500 ppm of the peroxyacetic acid, 6600 ppm of the hydrogen peroxide, 240 ppm of the HEDP, and 9 ppm of the DPA. Additionally, use on packaging for infant formula or human milk, or on aseptic filling equipment used to fill such packaging, is not included in this FCN.

No significant environmental release is expected upon the use of the subject FCS. This FCS will be used in processing plants throughout the United States, and wastewater containing the FCS subsequently generated at these facilities is expected to enter the wastewater treatment unit at the plants. It is assumed that treated wastewater will be discharged directly to surface waters in accordance with each plant's National Pollutant Discharge Elimination System (NPDES) permit.

Treatment of the process water is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. Sulfuric acid is listed as an optional ingredient in the FCS formulation, for the purpose of catalyzing the reaction between acetic acid and hydrogen peroxide, which will more rapidly produce a stable PAA (peroxyacetic acid) mixture and to adjust pH. As such, any addition of sulfuric acid to the FCS will be minimal, and thus is believed to have no significant effect on the environment.

Introduction of the HEDP and DPA into the environment will mainly result from disposal of wastewater into the processing plant wastewater treatment facility (either on-site or at a publicly owned treatment works plant). At the maximum use of this FCS under the proposed action, HEDP and DPA levels will be less than 240 ppm and 9 ppm, respectively (as mentioned above). Through treatment of the wastewater, approximately 80% of the HEDP will be absorbed into the sewage treatment sludge, as determined from data generated by the HERA project (Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates). Additionally, a 10-fold dilution factor is assumed for wastewater discharged to surface waters. As such, the final concentrations of HEDP and DPA in effluent would be 4.8 ppm and 0.9 ppm, respectively. These values are below the aquatic toxicity endpoints for the most sensitive species. Therefore, no significant environmental impacts from HEDP or DPA are anticipated.

Terrestrial introduction of HEDP will mainly result from sludge that ends up landfilled or land-applied. If the latter, HEDP is known to degrade in soil with a half-life of 373 days. Additionally, if the HEDP-containing sludge is disposed of in a landfill, HEDP would be expected to be controlled by the relevant EPA regulations, as well as state and/or local guidelines. When the HEDP is introduced to the environment, terrestrial and aquatic toxicity studies done also in the HERA project show that there would be no adverse effect on wild-life as a result of the maximum concentrations predicted for use of this FCS.

The notified use of this FCS mixture will not require any additional energy resources or raw materials to produce the FCS, as well as treatment and disposal of wastes compared with similar agents on the market.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2096 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 11-10-2020
Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 11-13-2020
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