Memorandum

Date: April 7, 2026

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Office of Pre-Market Additive Safety

To: Katherine Wilkening, Ph.D., Regulatory Review Scientist, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Brittany Ott, Ph.D., Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

BRITTANY OTT -S Digitally signed by BRITTANY OTT -S
Date: 2026.04.07 09:06:13 -04'00'

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2507

Notifier: Evonik Active Oxygens, LLC

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2507, which 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), 1-hydroxyethylidene-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). The FCS is for use as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice.

This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 17, 2026, 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.

ANTONETTA THOMPSON-WOOD -S Digitally signed by ANTONETTA THOMPSON-WOOD -S
Date: 2026.04.07 09:02:44 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI
File: FCN No. 2507

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2482, submitted by Evonik Active Oxygens, LLC 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), 1-hydroxyethylidene-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). The FCS is for use as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice. The components of the FCS on grains will not exceed: 350 ppm PAA, 1700 ppm HP, 12.5 ppm HEDP, 0.55 ppm DPA, and 25 ppm SA. The FCS is applied in the preparing, packing, or holding of food for commercial purposes, consistent with the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 201(q)(1)(B)(i). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Office of Pre-Market 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 March 17, 2026. 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 for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on wheat, corn, and rice grains in grain processing facilities.

Wastewater 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 treatment.

The complete and rapid degradation of PAA, HP, and AA is expected during the treatment of process wastewater or immediately after discharge of treated wastewater to the environment. Specifically, the PAA will decompose into oxygen, acetic acid, and water. While HP will decompose into oxygen and water. Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW as it is readily metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons and is practically totally dissociated at environmentally relevant concentrations which are not of environmental concern at the expected use levels. Sodium sulfate is widely distributed in nature. It occurs as mineral salts (e.g., thenardite, mirabilite); it is present in almost all fresh and salt waters, and sulfate as such is normally present in almost all natural foodstuffs. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of small amounts of sodium sulfate presents no significant hazard to the environment. 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 column. The maximum HEDP use level of 12.5 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 estimated environmental concentration (EEC) of 10 ppm for sludge, and 0.25 ppm for water. These concentrations are below the toxicity endpoints for soil (1000 mg/kg NOEC red worms) and water (10 ppm chronic NOEC for Daphnia magna). Therefore, there is no toxicity expected from any land

application of sludge containing 10 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.25 ppm HEDP is not expected to have toxic effects.

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 (0.55 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.055 ppm (i.e., EIC ÷ 10-fold dilution factor upon release of effluent to surface waters). There is limited 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[1], 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 7.69 mg/L for green algae, and 324 ppm 96 hr. LC50 for fish. The expected worst-case EEC of 0.055 ppm is below these concentrations. Therefore, discharge to surface waters of effluent containing 0.055 ppm DPA is not expected to have toxic effects on aquatic life.

Use of the FCS is not expected to have 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.

Manufacture of the FCS and its use as an antimicrobial will not require additional energy resources, as As evaluated in the EA, the proposed use of the FCS as described in FCN 2507 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by ANTONETTA THOMPSON-WOOD -S Digitally signed by ANTONETTA THOMPSON-WOOD -S Date: 2026.04.07 09:03:22 -04'00'

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[1] https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model