U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: August 19, 2022

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

To: Elizabeth Furukawa, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2242: An aqueous mixture of peroxycitric acid (PCA) (CAS Reg. No. 127542-89-6), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), citric acid (CAS Reg. No. 77-92-9), lactic acid (CAS Reg. No. 50-21-5), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9)

Notifier: Evonik Active Oxygens, LLC

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2022.08.19 14:10:56 -04'00'

Attached is the FONSI for FCN 2242 for the use of the above-described FCS as an antimicrobial agent used in process water, ice, or brine used in the production, processing, and preparation of poultry, meat, processed and pre-formed meat and poultry, fruits, vegetables, fish, and seafood.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated August 19, 2022, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Denis Wafula -S Digitally signed by Denis Wafula -S
Date: 2022.08.19 13:41:36 -04'00'

Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2242, submitted by Evonik Active Oxygens, LLC for the use of an aqueous mixture of peroxycitric acid (PCA) (CAS Reg. No. 127542-89-6), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), citric acid (CAS Reg. No. 77-92-9), lactic acid (CAS Reg. No. 50-21-5), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent used in process water, ice, or brine used in the production, processing, and preparation of poultry, meat, processed and pre-formed meat and poultry, fruits, vegetables, fish, and seafood.
The components of the FCS will not exceed:

1. 2000 ppm PCA, 2480 ppm HP, and 136 ppm HEDP in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs.
2. 495 ppm PCA, 1180 ppm HP, and 29 ppm HEDP in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed poultry.
3. 2000 ppm PCA, 2480 ppm HP, and 121.5 ppm HEDP in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut meat, including carcasses, parts, trim, and organs.
4. 495 ppm PCA, 1180 ppm HP, and 33.5 ppm HEDP in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed meat.
5. 600 ppm PCA, 1112 ppm HP, and 34 ppm HEDP in process water or ice used for washing, rinsing, chilling, or processing fruits and vegetables in food processing facilities.
6. 230 ppm PCA, 280 ppm HP, and 15 ppm HEDP in process water, ice, or brine used during commercial preparation of fish and seafood in food processing facilities.

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 August 19, 2022. 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 inhibit the growth of undesirable or pathogenic microorganisms in the process water and or the surface of the products.

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 PCA, HP, acetic acid and lactic acid is expected during treatment of the process wastewater or immediately after discharge of treated wastewater to the environment. Specifically, the PCA will breakdown during wastewater treatment into oxygen, water, and citric acid. While HP will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Most of the citric acid and lactic acid will be rapidly degraded during wastewater treatment prior to release into the environment. Sulfuric acid dissociates readily in water to sulfate ions 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. Thus, the focus of the environmental analysis is on HEDP. 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. The HEDP use level of 136 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 108.8 ppm for sludge, and 2.72 ppm for water. These concentrations are 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 any land application of sludge containing 108.8 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.72 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 2242 is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2022.08.19 13:42:18 -04'00' Date: see electronic signature

Denis Wafula, Ph.D.
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: 2022.08.19 14:11:36 -04'00' Date: see electronic signature

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