Memorandum

Date: July 22, 2025

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Review Team, Office of Food Chemical Safety, Dietary Supplements and Innovation, Office of Pre-Market Additive Safety

To: Sharon Koh-Fallet, Ph.D., Regulatory Chief, Regulatory Review Branch, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Chemical Safety, Dietary Supplements and Innovation, Office of Pre-Market Additive Safety

MARIELLEN PFEIL - Digitally signed by MARIELLEN PFEIL -S Date: 2025.07.22 12:00:35 -04'00'

Subject: Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2436

Notifier: Hydrite Chemical Co.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2436, 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), and optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9. The FCS is for use as an antimicrobial agent used in process water during the production of lactose, including for use as an ingredient in infant formula.

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 May 14, 2025, 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: 2025.07.22 10:06:25 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2436, submitted by Hydrite Chemical Co. for the use of 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), and optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9). The FCS is for use as an antimicrobial agent used in process water during the production of lactose. The components of the FCS will not exceed 33 ppm PAA, 155 ppm HP, 42 ppm AA and 1 ppm SA in process water used in the production of lactose, including for use as an ingredient in infant formula.

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 May 14, 2025. 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 in process water used in the production of lactose intended for use as a food ingredient for the general population and in infant formula. The FCS is for use in process water used in the manufacture of lactose.

The waste process water containing the FCS generated at lactose processing facilities is expected to enter the wastewater treatment unit at the food plants. It is assumed that very minor quantities of the mixture are lost to evaporation throughout the process, and that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption considered a worst-case scenario since it does not account for any further treatment that may occur at a Publicly Owned Treatment Works (POTW).

Treatment of the process water at an on-site wastewater treatment facility and/or at a POTW is expected to result in complete degradation of PAA, HP, and AA peroxyacetic acid, hydrogen peroxide, and acetic acid. Specifically, the PAA will break down into oxygen and AA. While HP will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Therefore, these substances are not expected to be introduced into the environment to any significant extent when the FCS is used as intended. 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. Sulfate ions are either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate due to participation in the natural sulfur cycle. Therefore, any terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are expected to have no significant environmental impact, as sulfate is a ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources.

Manufacture of the FCS and its use as an antimicrobial will not require additional energy resources, as the FCS is expected to compete with and/or replace similar antimicrobial agents such as other peroxyacetic acid-based antimicrobial agents that are already on the market. No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal the FCS,

As evaluated in the EA, the proposed use of the FCS as described in FCN 2436 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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Antonetta Thompson-Wood, M.S.
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Approved by

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Mariellen Pfeil
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