

Memorandum

Date: September 15, 2025

From: Biologist, Environmental Team, Office of Pre-Market Additive Safety

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2464

Notifier: Hydrite Chemical Co.

To: Sean Fischer, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety

Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

MARIELLEN PFEIL - Digitally signed by MARIELLEN PFEIL -S
Date: 2025.09.15 13:30:26 -0400

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2464, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2464 is for the use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), and optionally, sulfuric acid (SA) (79-21-0; 7722-84-1; 64-19-7; 7664-93-9), as an antimicrobial additive to liquid, pasteurized whey used in the production of whey protein concentrate and whey protein isolate, including whey protein concentrate and whey protein isolate used as an ingredient in infant formula.

The components of the FCS will not exceed 16 ppm PAA, 76 ppm HP, 21 ppm AA, and 1 ppm SA in the whey solution used to manufacture whey protein concentrate and whey protein isolate, including whey protein concentrate and whey protein isolate used as an ingredient in infant formula.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated July 15, 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.

Brittany Ott -S Digitally signed by Brittany Ott -S
Date: 2025.09.15 08:43:02 -0400
Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2464, submitted by Hydrite Chemical Co. for the use of aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), and optionally, sulfuric acid (SA), an antimicrobial additive to liquid, pasteurized whey used in the production of whey protein concentrate and whey protein isolate, including whey protein concentrate and whey protein isolate used as an ingredient in infant formula.

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 July 15, 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.

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. Additionally, sulfuric acid dissociates readily in water, and so at environmentally relevant concentrations, sulfuric acid is practically totally dissociated.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its use as an antimicrobial agent applied to foods will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2464 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Brittany Ott -S

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Prepared by _____

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

Office of Food Chemical Safety, Dietary Supplements & Innovation
Human Foods Program
Food and Drug Administration

Approved by

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Mariellen Pfeil
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