

Memorandum

Date: July 7, 2026

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Review 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: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
Date: 2026.07.07 15:46:41 -0400

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2517

Notifier: Buckman Laboratories, Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2517, which is for the use of 2-Propenoic acid, 2-methyl, polymers with acrylamide, hydrolyzed poly(vinyl acetate) and 2-hydroxyethyl methacrylate (CAS Reg. No. 2349398-97-4) as a creping agent in the manufacture of paper.

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 February 26, 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
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Date: 2026.07.07 15:42:27 -0400

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2517, submitted by Buckman Laboratories, Inc., for the use of 2-Propenoic acid, 2-methyl, polymers with acrylamide, hydrolyzed poly(vinyl acetate) and 2-hydroxyethyl methacrylate (CAS Reg. No. 2349398-97-4) for use as a creping agent in the manufacture of paper. The FCS may be used at levels not to exceed 25.4 µg/in² of finished paper. The FCS may be used in contact with all food types under Conditions of Use A through H as described in Tables 1 and 2. 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 February 26, 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 used as a protective coating on the Yankee drying cylinder in the tissue paper making process. The FCS is diluted and then sprayed onto the Yankee cylinder to protect the metal surface against abrasion by the creping blade of the machine. The FCS provides high wet tack (bonding) that enables the Yankee cylinder to pick up the formed tissue sheet and hold it until it is creped by the doctor blade. The creping process gives tissue paper products their characteristic densities and textures. The tissue paper may be used in the packing or transport of food, e.g., bakery products. The FCS can be used as an alternative to traditional polyvinyl alcohol, which is hard to heat, difficult to stock and has a short shelf life.

Manufacture of the FCS is not expected to result in significant environmental impact. Manufacture of food-contact articles containing the FCS is also not expected to result in a significant impact to the environment. The FCS is incorporated into the finished tissue and is expected to remain with these materials throughout use and disposal of the finished food-contact material by the consumer. When the FCS is used in coatings on food-contact articles, the process is a dry-end application, and all the FCS remains with the coating, and all the coating remains on the food-contact article. Disposal of paper containing the FCS will be via municipal solid waste (MSW) disposal into landfills or to MSW combustors or recycled corresponding with disposal rates from The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Tables and Figures.¹

Post-consumer disposal of food-contact articles containing the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Due to EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. Further, because of the regulations at 40 CFR Part 60, and others, no significant impacts are expected from incineration of the FCS at MWCs. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

¹ https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of similar creping agents that are already permitted for use in food contact articles. Articles containing the FCS are expected to be disposed of according to the same patterns when used in place of current similar materials. Therefore, no net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected.

No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2517 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
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