Memorandum

Date: June 9, 2026

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

To: Lillian Mawby, 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: 2026.06.10 10:38:35 -04'00'

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2519

Notifier: Advancion Corporation

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2519, which is for the use of 3-Amino-3-methyl-2-butanol (AMB; CAS Reg. No. 13325-14-9) as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard.

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 11, 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 -S
Date: 2026.06.09 06:57:58 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2519, submitted by Advancion Corporation, for the use of 3-Amino-3-methyl-2-butanol (AMB; CAS Reg. No. 13325-14-9) as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard. The FCS will be used as a component of: 1) coatings at a level not to exceed 0.25% by weight of the mineral pigment 2) fillers at a level not to exceed 0.05% by weight of the mineral pigment. The finished paper and paperboard may contact all food types under Conditions of Use A through H, and J (microwave-only, excluding susceptor applications). 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 FCS is intended for use as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard. The FCS will provide various mineral pigment processing benefits, such as increased brightness, opacity and cost-efficiency of manufacture.

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 11, 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.

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. 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. Therefore, finished paper and paperboard containing the FCS will be recycled or disposed of via municipal solid waste (MSW) disposal into landfills or to MSW combustors corresponding with disposal rates from The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Tables and Figures.[1] On the other hand, when the FCS is used as a filler, the process is a wet-end application, and because the FCS is highly soluble in water is expected to be lost with the white water associated with paper making. The FCS is not expected to significantly adsorb to sewage sludge as demonstrated by the low Kow partition coefficient.

During the wet-end papermaking process, the FCS is expected to partition into and remain with the processing whitewater. Following an approximate 85% biodegradation during wastewater treatment and a 10-fold dilution into surface water the estimated environmental concentration (EEC) is 0.36 mg/kg (equivalent to 0.36 mg/L). This value is 278-fold below the acute No Observed Effect Concentration (NOEC) of 100 mg/L, and more than 278-fold below the acute half-maximal effective concentration (EC50) / lethal concentration (LC50) for the aquatic species tested. The EEC of 0.36 mg/L is 35-fold lower than the subchronic NOEC of 12.5 mg/L. Thus, the FCS is not expected to have any significant effect on aquatic organisms.

As noted above, when the FCS is used in coatings for paper and paperboard, the anticipated routes of disposal after use are expected to be recycling, landfilling or combustion in MSW incinerators. Post-

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

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.

The FCS is not expected to impact recyclability as clay, titanium dioxide or calcium carbonate coated paper is typical in the recycling stream, and the FCS is 0.01% in the finished paper.

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of chemically related substances now on the market. 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 2519 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: 2026.06.09 06:58:23 -04'00'

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