Memorandum

Date: April 13, 2026

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

To: Laura Markley, Ph.D., Regulatory Review Scientist, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Denis Wafula, Ph.D., Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

Denis Wafula - S Digitally signed by Denis Wafula -S Date: 2026.04.13 10:28:58 -04'00'

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2496

Notifier: Troy Corporation, an Arxada Company

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2496, which is for the use of 1,2-Benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5). The FCS is for use: (1) As a biocide preservative in aqueous latex/silicone formulations used for coatings on metal substrates complying with 21 CFR § 175.300 and on polypropylene (PP) films complying with 21 CFR § 175.320; and (2) as an antimicrobial agent in can-end and side-seam cements.

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 November 25, 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: 2026.04.13 09:17:45 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2496, submitted by Troy Corporation, an Arxada Company, for the use of 1,2-Benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5). The FCS is for use: (1) As a biocide preservative in aqueous latex/silicone formulations used for coatings on metal substrates complying with 21 CFR § 175.300 and on polypropylene (PP) films complying with 21 CFR § 175.320; and (2) as an antimicrobial agent in can-end and side-seam cements. The limitations/specifications of the FCS are: (1) For use as a biocide preservative at a level not to exceed 5 percent by weight of the preservative formulation, which may be added to the latex/silicone formulations at a level not to exceed 0.3 percent by weight. Coatings containing the FCS may not exceed an applied coating rate of 7.74 mg/in2. The FCS is intended for contact with all food types, under Conditions of Use A through H, as described in Tables 1 and 2. (2) For use at levels not to exceed 0.015 percent by weight (150 parts per million, ppm) in can-end and side-seam cements that will contact aqueous, acidic, low alcoholic (up to 8 percent v/v alcohol content) and fatty food under Conditions of Use A through H, and high alcoholic food (greater than 8 percent alcohol content) under Conditions of Use C through G, 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 November 25, 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 a preservative used in the production of food-packaging materials.

The FCS is expected to be entirely incorporated into finished articles and will remain with the finished food-contact articles throughout the use and disposal. Any waste materials generated in this process, e.g., plant scraps, are expected to be disposed of as part of the finished article manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the population density and will be widely distributed across the country. Disposal, recycling, and combustion rates of food contact articles manufactured with the FCS will correspond with 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/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

Further, according to data cited in the EA, when combusted, there is nothing to suggest that the FCS would threaten a violation of 40 CFR 60 or other regulations governing MWCs.

Manufacture of the FCS will consume comparable amounts of energy and resources because the FCS is expected to compete with, and to some extent replace similar substances already on the market such as those indicated in FCN 1108. Articles containing the FCS are expected to be disposed of according to the same patterns when used in place of current 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 2496 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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Prepared by _____

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