U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: February 20, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2498

Notifier: Laboratorios Argenol SL

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

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

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2026.02.20 14:03:07 -05'00'

Attached is the FONSI for FCN 2498, which is for the use of silver-zinc-calcium-sodium-borate-phosphate glass as an antimicrobial agent in food contact polymers. 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 January 22, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2026.02.20 13:28:15 -05'00'

Denis Wafula, Ph.D.

Attachment: Finding of No Significant Impact

File: FCN No. 2498

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2498, submitted by Laboratorios Argenol SL, for the use of silver-zinc-calcium-sodium-borate-phosphate glass intended for use as an antimicrobial agent in food contact polymers. The FCS will be used at levels not to exceed 1.0 percent by weight of the finished article in which the silver content of the finished article shall not exceed 0.022 percent by weight. Finished articles containing the FCS may contact all food types under Conditions of Use A through H, as described in Tables 1 and 2.[1] The FCS is not for use in contact with infant formula or 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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment, dated January 22, 2026. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Food-contact articles containing the FCS are expected to be disposed by either landfilling or by incineration at municipal solid waste (MSW) combustors. Recycling is not anticipated to be a major method of disposal. All pathways of disposal will occur at rates proportional to the national MSW disposal patterns for similar products. It is anticipated that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of such articles. Further, under 40 CFR 261.24, silver is a toxic hazardous waste (waste code D011) if detected at concentrations ≥ 5 mg/L using the Toxicity Characteristic Leaching Procedure (TCLP) (EPA Method 1311). Accordingly, the notifier evaluated the potential for silver to leach from landfilled wastes. The migration studies indicate that disposal of articles containing the FCS in landfills is not expected to release silver at significant levels. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60. Because of its composition, incineration of the FCS will not produce greenhouse gas (GHG) emissions

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected be used in place of similar substances that are already in use. Manufacture of the FCS and its use in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of chemically related substances 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.

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

Consequently, we find that use of the FCS as an antimicrobial agent in food contact polymers will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2026.02.20 13:29:21 -05'00'

Denis Wafula, Ph.D.
Biologist, Environmental Review Team
Office of Pre-Market Additive Safety
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Human Foods Program
Food and Drug Administration

Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2026.02.20 14:04:45 -05'00'

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