

Memorandum

Date: July 30, 2026

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

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2514

Notifier: Jiangsu Evergreen New Material Technology Incorporated Company

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

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

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
Date: 2026.07.30 13:25:23 -0400

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2514, which is for the use of triisotridecyl phosphite (CAS Reg. No. 77745-66-5) as an antioxidant in vinyl chloride polymers and linear low-density polyethylene.

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 2, 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.

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Date: 2026.07.30 13:07:17 -0400

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2514, submitted by Jiangsu Evergreen New Material Technology Incorporated Company for the use of triisotridecyl phosphite (CAS Reg. No. 77745-66-5) as an antioxidant in vinyl chloride polymers and linear low-density polyethylene. The FCS is proposed for use 1) at levels not to exceed 1 percent by weight of finished vinyl chloride polymers in contact with all food types under Conditions of Use B through H, as described in FDA Table 2 and 2) at levels not to exceed 0.25 percent by weight in linear low-density polyethylene complying with 21 CFR 177.1520(c), items 3.1 and 3.2, where the density of the polymer is not greater than 0.94 grams per cubic centimeter. Linear low density polyethylene articles containing the FCS may be used in contact with dry (with no free surface fat or oil), aqueous, acidic, and alcoholic food (up to 15 percent alcohol), under Conditions of Use B through H, as described in FDA Table 2. The FCS may contain no more than 1 percent by weight triisopropanolamine (CAS Reg. No. 122-20-3). 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 2, 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 intended to be used as an antioxidant in polymeric food-contact materials. The FCS inhibits oxidation and deterioration of technical performance of polymers used in food-contact materials.

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's (US EPA) Advancing Sustainable Materials Management: 2018 Tables and Figures¹.

No significant environmental release is expected upon the use of materials containing the FCS. 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.

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/default/files/2020-11/documents/2018_ff_fact_sheet.pdf

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources as manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative FCS. The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market.

Food-contact materials and articles containing the FCS are expected to be disposed of according to the same patterns when it is used in place of current materials. Therefore, there will be no anticipated impact on current or future recycling programs.

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 2514 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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