U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: May 6, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2490

Notifier: SI Group

To: Adriana Alexander, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety
Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2490, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2490 is for the use of a Cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6), as an antioxidant and/or stabilizer in polyethylene terephthalate (PET) polymers.

The FCS will be used at levels not to exceed 0.2 percent by weight of finished PET polymers in contact with all food types under Condition of Use A through H, as described in Tables 1 and 2. The FCS may be used in conjunction with triisopropanolamine (CAS Reg. No. 122-20-3) at a maximum use level of 1 percent by weight of the FCS. 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.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated January 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.

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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

File: FCN No. 2490

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2490, submitted by SI Group for the use of Cyclic neopentanetetrayl bis(octadecyl phosphite), an antioxidant and/or stabilizer in polyethylene terephthalate (PET) polymers, excluding contact with infant formula and human milk.

The Office of Food 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 January 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 expected to be entirely incorporated into and remain with the finished food-contact polymer and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures. The FCS is expected to be utilized in patterns corresponding to the population density and then disposed of nationwide. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population density and then disposed of nationwide via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.[1] The EA indicates that the fate of articles containing the FCS within MSW is as follows: approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting) and 6.1% was processed through other food management pathways.

Regarding PET bottles specifically, the National Association for PET Container Resources (NAPCOR) estimates that 28% of PET bottles were recycled in 2019[2]. It is anticipated that the PET manufactured containing the FCS would be marked with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made and thus coded for identification as PET[3]. Using this recycling rate for PET bottles, specifically, it is calculated that 13.1% of the food-contact materials containing the FCS will be combusted annually (11.8% combusted ÷ (11.8% combusted + 28% recycled + 50% land disposed) = 13.1% combusted. The low use level of the FCS in food-contact materials is not expected to impact the disposal patterns of the polymeric resins in which it is used.

Post-consumer disposal of food-contact articles manufactured with the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected annual carbon dioxide equivalent emissions, calculated according to the confidential annual market volume, are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

The FCS does not readily volatilize; as such, it is unlikely to present any impact on the atmospheric environment. Virtually no leaching of potential migrants from the finished food-contact article into aquatic or terrestrial environments indicates that there is no anticipated significant impact on environmental concentrations of the FCS, including during combustion of the food-contact articles. Thus, no significant impact on the concentrations

[1]Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020 (https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).
[2] See National Association for PET Container Resources (NAPCOR), NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow, available at: https://napcor.com/news/4970-2/ (last accessed April 1, 2023).
[3] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, no significant impacts are expected from incineration of the FCS at MWCs.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of materials 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2490 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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