Memorandum

Date: April 14, 2026

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

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

Through: Brittany Ott, P.D., Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

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Date: 2026.04.14 10:48:23 -04'00'

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2510

Notifier: Setaş Kimya Sanayi A.Ş.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2510, which is for the use of Tricyclodecanedimethanol (CAS Reg. No. 26160-83-8 and 26896-48-0) as a monomer in the manufacture of (1) polyester or polyester/polyurethane resins for use as components of coatings for use on metal substrates and repeated-use food-contact surfaces, or (2) polyester resins for use in adhesives.

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 29, 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-WOOD -S
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Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2510, submitted by Setaş Kimya Sanayi A.Ş. for the use of Tricyclodecanedimethanol (CAS Reg. No. 26160-83-8 and 26896-48-0). The FCS is for use as a monomer in the manufacture of (1) polyester or polyester/polyurethane resins for use as components of coatings for use on metal substrates and repeated-use food-contact surfaces, or (2) polyester resins for use in adhesives. The level of the FCS in the final coating may not exceed 46.1 percent by weight. Coatings containing the FCS may contact all food types under Conditions of Use A through H, as described in Tables 1 and 2. Polyester-based adhesives containing the FCS shall comply with 21 CFR 175.105 or 21 CFR 175.125 and will be used at room temperature or below. 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 in the production of polyester resins that will be used in food-contact materials, i.e., adhesive applications. Use of the FCS monomer in polyesters provides high glass transition temperature and improved adhesion to metallic and other substrates.

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 January 29, 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 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.

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 Fact Sheet.[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.

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.

[1] https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of chemically related resins. 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 (i.e., competitive polyester resins made with other alcohol monomers); therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2510 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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Approved by

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