U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: February 3, 2025

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2406

Notifier: Chitec Technology Co., Ltd.

To: Anita Chang, Ph.D.
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: 2025.02.03 17:33:28 -05'00'

Attached is the FONSI for FCN 2406, which is for the use of [4-tert-butyl-2-(5-tert-butyl-2-oxo-3H-benzofuran-3-yl)phenyl] 3,5-ditertbutyl-4-hydroxy-benzoate (CAS Reg. No. 1261240-30-5) in polyolefin articles. 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 30,2024 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: 2025.02.03 17:28:45 -05'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2406, submitted by Chitec Technology Co., Ltd. for the use of [4-tert-butyl-2-(5-tert-butyl-2-oxo-3H-benzofuran-3-yl)phenyl] 3,5-ditertbutyl-4-hydroxy-benzoate (CAS Reg. No. 1261240-30-5) in polyolefin articles. The FCS will be blended with hindered phenolic and phosphite-based antioxidants to provide a synergistic effect. The FCS may be used at a level up to 1) 500 ppm in polyolefin articles in contact with aqueous and acidic foods under Conditions of Use (COU) A through H; and 2) 100 ppm in polypropylene articles (thickness shall not exceed 10 mil) in contact with dry, alcoholic and fatty foods under COU A through H as described in Tables 1 and 2.[1] 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 30, 2024. 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 article and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in the process of fabricating food-contact articles containing the FCS are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Items manufactured with the FCS are expected to be land disposed or combusted in proportions corresponding to the patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2018 Tables and Figures." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Since these items will not be recycled, they will not interfere with recycling patterns. Because of the aforementioned MSW landfill regulations and its chemical properties, the FCS is not expected to leach into the environment. Further, the FCS does not readily volatilize and therefore it is not expected to present any impact on the atmosphere. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

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. It is reasonable to expect that the manufacture of the FCS and its fabrication in food-contact articles 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

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

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 2406 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2025.02.03 17:29:33 -05'

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

Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.02.03 17:34:00 -05'00'

Mariellen Pfeil
Lead Biologist, Environmental Review Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
Food and Drug Administration