



Memorandum

Date: December 10, 2024

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2402

Notifier: Unitika LTD

To: Nicole Morris-Anastasi, Ph.D.
Office of Pre-Market and Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist, Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2024.12.10 22:26:45 -05'00'
Office of Pre-Market and Additive Safety, Environmental Review Team

Attached is the FONSI for FCN 2402, which is for the use of polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified) prepared by the condensation of terephthalic acid and isophthalic acid with ethylene glycol in films intended for contact with aqueous, acidic, fatty, alcoholic, and dry foods. 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 September 5, 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: 2024.12.10 16:56:14 -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) 2402, submitted by Unitika LTD for the use of polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified) prepared by the condensation of terephthalic acid and isophthalic acid with ethylene glycol as films intended for contact with aqueous, acidic, fatty, alcoholic foods (containing up to 50 percent alcohol by volume), and dry foods under Conditions of Use A through H as described in Table 2,¹ and for use in contact with alcoholic foods containing more than 50 percent alcohol by volume under Conditions of Use E through G, as described in Table 2. The finished polymer shall contain a total of not more than 13 mole-percent of diethylene glycol and isophthalate units, with the diethylene glycol content expressed as a mole-percent of the total glycol units and the isophthalate content expressed as a mole-percent of the total isophthalate/terephthalate units. The finished food-contact film shall have a maximum thickness of 50 µm and must meet any applicable specifications and is subject to all applicable conditions of use cited in 21 CFR 177.1630(f), (g), and/or (j). Adjuvant substances permitted for use in polymers complying with 21 CFR 177.1630 may be used in the copolyesters that are the subject of this notification, subject to any applicable limitations. 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 and 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 September 5, 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, recycled, or combusted proportionately with disposal 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. Because identical polyester materials are currently recycled and because current plastics manufacturing practices include polymer identification coding, impacts to recycling are not anticipated. 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

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

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 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 2402 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
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Denis Wafula, Ph.D.
Biologist, Environmental Review Team
Office of Pre-Market and Additive Safety
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Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
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