

Memorandum

Date: July 22, 2025

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2432

Notifier: Arkema, Inc.

To: Lillian Mawby, 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

MARIELLEN PFEIL -S

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2432, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2432 is for the use of an Hexanedioic acid, polymer with azacyclotridecan-2-one and α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl) (70290-02-7), as a processing aid in olefin polymers.

The FCS will be used at levels not to exceed 1050 ppm by weight in finished olefin polymers in contact with all food types, under Conditions of Use A through H, as described in Tables 1 and 2. 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 April 29, 2025 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.

Brittany Ott -S

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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2432, submitted by Arkema, Inc. for the use of Hexanedioic acid, polymer with azacyclotridecan-2-one and α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl), a processing aid in olefin 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 April 29, 2025. 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. However, as the FCS is expected to be disposed of primarily by land-filling or combustion (i.e. not recovered for recycling), it is estimated that 19.1% of the food-contact materials containing the FCS will be combusted annually, while the remaining 80.9% will be land-disposed.²

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 FCS does not readily volatilize due to it being a high molecular weight polymer; 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 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.

The maximum annual market volume³ of the food-contact polymers containing the FCS was compared to the annual plastic containers and packaging waste (14,530 thousand tons in 2018⁴), and it was concluded that the

¹Advancing 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 This amount is calculated as follows: 11.8% combusted \div (11.8% combusted + 50% land disposed) = 19.1% combusted.

³ This information was presented to the FDA in a Confidential Attachment.

⁴ *Ibid*

FCS and the food-contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste present in MSW.

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 2432 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Brittany Ott - S



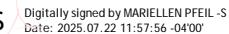
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Prepared by

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

MARIELLEN PFEIL -S



Digitally signed by MARIELLEN PFEIL -S

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Approved by

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