U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: January 21, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2475

Notifier: Innospec Ltd.

To: Joshua Moskowitz, Ph.D., Regulatory Review Scientist, Office of Pre-Market Additive Safety
Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2026.01.21 15:21:08 -05'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2475, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2475 is for the use of an mixture of 1-decene, polymer with sulfur dioxide; 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane; and dodecylbenzenesulfonic acid (CAS Reg. No. 33990-98-6; 1010121-89-7; 27176-87-0), as 1) an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers used in food-contact applications, including use in infant formula and human milk; and 2) an antistatic agent in the production of high-density polyethylene polymers used in repeat-use food-contact applications, except for use in contact with infant formula and human milk.

Limits and Specifications:

1. For use at levels not to exceed 12 parts per million (ppm) in articles in contact with infant formula and human milk under Conditions of Use A through H, as described in Table 2; and for use at levels not to exceed 60 parts per million (ppm) in articles in contact with all other food types under Conditions of Use A through H, as described in Tables 1 and 2.

2. For use at levels not to exceed 280 parts per million (ppm) at a maximum use temperature of 175 °C in repeat-use articles in contact with all food types, except for use in contact with infant formula and human milk. 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 December 10, 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.

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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

File: FCN No. 2475

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2475, submitted by Innospec Ltd. for the use of mixture of 1-decene, polymer with sulfur dioxide; 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane; and dodecylbenzenesulfonic acid, as 1) an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers used in food-contact applications, including use in infant formula and human milk; and 2) an antistatic agent in the production of high-density polyethylene polymers used in repeat-use food-contact applications, except for use in 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 December 10, 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 80.9% of municipal solids waste is currently deposited in land disposal sites, with 19.1% being combusted.[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 elements of the FCS are either typical of MSW (i.e. C, H, N, and O) or are mitigated via the Clear Air Act regulations (i.e. S may contribute to sulfur dioxide or SOX emissions).[3]

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[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] According to the United States Environmental Protection Agency's 2020 update of data regarding municipal solid waste in the United States, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered for recycling or composting. However, the disposal pattern was recalculated here based on only the quantities of MSW that are land disposed or combusted as the FCS is not recovered for recycling. Therefore, it was estimated that approximately 19.1% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. It is thus anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

[3] Section 129 of the Clean Air Act (CAA) directs the Administrator to develop regulations under section 111 of the Act limiting emissions of nine air pollutants (*i.e.*, particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from four categories of solid waste incineration units: municipal solid waste; hospital, medical and infectious solid waste; commercial and industrial solid waste; and other solid waste." *See* https://www.epa.gov/stationary-sources-air-pollution/small-municipal-waste-combustors-smwc-new-source-performance and https://www.epa.gov/stationary-sources-air-pollution/large-municipal-waste-combustors-lmwc-new-source-performance.

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.

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 2475 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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