U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: March 30, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2473

Notifier: Clariant Corporation

To: Sharon Koh-Fallet, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety
Through: Antonetta Thompson-Wood, Physical Scientist, Environmental Review Team, Office of Pre-Market Additive Safety

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2473, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2473 is for the use of Rice bran wax, oxidized (CAS Reg. No. 1883583-80-9) and its calcium salt (CAS Reg. No. 1850357-57-1), as a processing aid, lubricant, release agent, and/or slip additive in single- and repeat-use rigid polyvinyl chloride.

For use at levels not to exceed 0.5% in rigid polyvinyl chloride that contacts all food types at temperatures up to 80 °C. 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 January 7, 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.

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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

File: FCN No. 2473

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2473, submitted by Clariant Corporation for the use of Rice bran wax, oxidized (CAS Reg. No. 1883583-80-9) and its calcium salt (CAS Reg. No. 1850357-57-1), a processing aid, lubricant, release agent, and/or slip additive in single- and repeat-use rigid polyvinyl chloride, 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 January 7, 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 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; as the FCS is expected to be primarily disposed of through combustion or land-filling (i.e., not recycled, composted, or handled through other food management pathways), the disposal pattern is recalculated based on only the quantities of MSW that are land disposed or combusted. On this basis, it is estimated that 19.1% of food-contact materials containing the FCS will be combusted annually.

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.

Plant waxes, such as rice bran wax, are produced in the epidermal cells of most plants and exuded onto the cell surface. The extremely small or nonexistent environmental introduction concentrations associated with the disposal of packaging containing the FCS could not alter the natural background concentrations of plant waxes and their components in the environment.

The FCS does not readily volatilize; 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.

[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).

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 2473 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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