

## Memorandum

**Date:** April 18, 2024

**From:** Biologist, Environmental Team, Division of Science and Technology (HFS-255)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2359

**Notifier:** Omya International AG and its affiliates

**To:** Nicole Morris-Anastasi, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

**Through:** Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S  
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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2359, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2359 is for the use of 2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivs., as a surface treatment for calcium carbonate, used as a pigment and/or filler in food contact materials and articles, except for use in contact with infant formula and human milk.

The FCS contained in the calcium carbonate may be present at levels of up to 0.85 weight percent in cellulose acetate, polyamide, and polycarbonate materials and articles. The finished materials and articles will be used in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2 (see Enclosure 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.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated January 31, 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.

**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) 2359, submitted by Omya International AG and its affiliates is for the use of 2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivs., as a surface treatment for calcium carbonate, used as a pigment and/or filler in food contact materials and articles, excluding contact with infant formula and human milk, as specified below.

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 24, 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 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. 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*.<sup>1</sup> As such, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to 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 was 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. The expected annual carbon dioxide equivalent emissions, calculated according to the confidential annual market volume, are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

Minimal 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.

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<sup>1</sup> 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](https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf)).

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 2359 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Brittany Ott -S** Digitally signed by Brittany Ott -S  
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