Memorandum

Date: December 21, 2021

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2187: 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine (CAS Reg. No. 32687-78-8).

Notifier: SONGWON International AG

To: Elizabeth Furukawa, 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)

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2187, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2187 is for the use of 1,2-bis(3,5-di-tertbutyl-4-hydroxyhydrocinnamoyl)hydrazine as a stabilizer and antioxidant in polyolefin polymers and copolymers, except for use in contact with infant formula and human milk, under the following specifications:

1) In high density polyethylene (HDPE) at levels not to exceed 0.12 percent by weight of finished articles in contact with all food types under Conditions of Use B through H [1];
2) In polypropylene (PP) and PP copolymers at levels not to exceed 0.12 percent by weight of finished articles in contact with all food types under Conditions of Use B through H;
3) In polyethylene copolymers as described in 21 CFR 177.1520(c), item 3.2a[2] at levels not to exceed 0.18 percent by weight of finished articles in contact with aqueous and acidic foods under Conditions of Use B through H; and
4) In polyolefin at levels not to exceed 0.12 percent by weight of finished repeat-use articles in contact with all food types.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated September 22, 2021 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 (digitally signed 12-21-2021)

Attachments: Finding of No Significant Impact (FONSI)

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-usefood-contact-substances
[2] Part C, Specifications Table

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2187, submitted by SONGWON International AG for the use of 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine as a stabilizer and antioxidant in polyolefin polymers and copolymers, except for use in 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 September 22, 2021. 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 intended for use as a stabilizer and antioxidant in polyolefin polymers and copolymers, except in contact with infant formula and human milk, under the following specifications:

1) In high density polyethylene (HDPE) at levels not to exceed 0.12 percent by weight of finished articles in contact with all food types under Conditions of Use B through H[3];
2) In polypropylene (PP) and PP copolymers at levels not to exceed 0.12 percent by weight of finished articles in contact with all food types under Conditions of Use B through H;
3) In polyethylene copolymers as described in 21 CFR 177.1520(c), item 3.2a [4] at levels not to exceed 0.18 percent by weight of finished articles in contact with aqueous and acidic foods under Conditions of Use B through H; and
4) In polyolefin at levels not to exceed 0.12 percent by weight of finished repeat-use articles in contact with all food types.

The notifier does not intend to produce finished food-contact articles containing the FCS; rather, the FCS will be sold to food-contact article manufacturers who will then produce the food-contact materials. Any waste materials generated in the process of producing the pads is 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 and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*. [5] Post-consumer disposal of food-contact articles containing the FCS will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Articles manufactured with the FCS are not expected to be recycled. EPA's regulations

[3] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-usefood-contact-substances

[4] Part C, Specifications Table

[5] We note that in Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA. Please see the following links:

- https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf
- https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

We note that this report does not impact the conclusions presented in the EA, so no revision was required. However, the notifier was advised to utilize these reports in their future submissions.

governing landfills at 40 CFR Part 258, preclude leaching into the environment from food-contact articles manufactured with the FCS. Additionally, a full assessment of greenhouse gas (GHG) emissions is provided in a confidential attachment to the EA. Based on estimated market volume information provided in a confidential attachment to the EA, the total annual emissions of the greenhouse gases (GHG) resulting from combustion of items manufactured with the FCS are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. [6]

Finally, the FCS does not readily volatize and is expected to remain with the finished food-contact article. 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. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2187 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 12-21-2021
Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-21-2021
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[6] This statement is supported by data contained in a Confidential Attachment provided by the notifier in conjunction with the EA.