U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: June 16, 2023

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2290: 1,2-Bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl) hydrazine

Notifier: Rianlon Corporation

To: Stevie Bush, 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 Digitally signed by Mariellen Pfeil -S Date: 2023.06.16 12:47:50 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2290, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2290 is for the use of 1,2-Bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl) hydrazine, for use as an antioxidant in polyolefin polymers and copolymers under the following Limitations/Specifications. The FCS may be used in:

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

The FCS is also not intended for contact with infant formula and human milk; such uses were thus no 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 May 4, 2023 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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Attachment: Finding of No Significant Impact (FONSI)

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

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2290, submitted by Rianlon Corporation for the use of 1,2-Bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl) hydrazine as an antioxidant in polyolefin polymers and copolymers, intended to contact food all food types, excluding 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 May 4, 2023. 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 an antioxidant in polyolefin polymers and copolymers under the following Limitations/Specifications.

The FCS may be used in:

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

The FCS is expected to be entirely incorporated into and remain with the finished food-contact article 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 packaging manufacturer's overall non-hazardous solid waste in accordance with established procedures. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration). Recycling is not anticipated; as such, it is calculated that 80.9% of the materials will be deposited in landfill sites, while 19.1% will be combusted[3].

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*. Post-consumer disposal of food-contact articles

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

[3] Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and manage in the United States, EPA530-F-20-009, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), December 2020, available at Advancing Sustainable Materials Management: 2018 Fact Sheet {epa.gov). According to this report, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted with energy recovery, 32.1 % was recovered (a combination of waste recovered for recycling and for composting) and 6.1 % processed through other food management pathways. If we assume that food-contact articles containing the FCS are expected to be disposed of by landfilling or combustion (i.e., not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.1 % of food-contact articles 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. The remaining 80.9% will be land-disposed.

containing the FCS will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected carbon dioxide equivalent emissions are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

Finally, as the FCS is a high melting point solid, it does not readily volatize and virtually no leaching is expected; the FCS is therefore 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 2290 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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Prepared by

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Approved by

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