U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 20, 2024

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

To: Kenneth McAdams , Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2349

Notifier: Rianlon Corporation

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2024.02.21 17:06:21 -05'00'

Attached is the FONSI for FCN 2349, which is for the use of Tris(2,4-di-tert-butylphenyl)phosphite (CAS Reg. No. 31570-04-4) as an antioxidant/stabilizer in olefin copolymers complying with 21 CFR 177.1520(c), items 3.2c, 3.4, or 3.6, or in styrene block copolymers for use in contact with food. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated February 6, 2024, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2024.02.20 16:16:18 -05'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2349, submitted Rianlon Corporation for the use of Tris(2,4-di-tert-butylphenyl)phosphite (CAS Reg. No. 31570-04-4) as an antioxidant/stabilizer in olefin copolymers complying with 21 CFR 177.1520(c), items 3.2c, 3.4, or 3.6, or in styrene block copolymers for use in contact with food. The FCS is to be used at levels not to exceed 0.2 weight percent of the finished articles when used in olefin copolymers and at levels not to exceed 0.4 weight percent of the finished articles when used in styrene block copolymers. The finished articles containing the FCS may be used in contact with all food types under Conditions of Use A through H as described in Tables 1 and 2,[1] subject to limitations of the base polymer. 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.

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 February 6, 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 and is briefly summarized below.

Food-contact articles containing the FCS are expected to be disposed by landfilling, recycling, or incineration at municipal solid waste (MSW) combustors proportional to the current national municipal solid waste disposal patterns. It is anticipated that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of food-contact articles containing the FCS. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. The FCS is not expected to affect recycling because polymer additives are commonly encountered in the recycling stream. Based upon an analysis using market volume information provided in the confidential attachment to the EA, total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

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 and its use in food-contact articles 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.

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

The use of the FCS, as described in FCN 2349, as an antioxidant/stabilizer food-contact articles will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2024.02.20 16:16:49 -05'00'

Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2024.02.21 17:07:17 -05'00'

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