U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 14, 2023

From: Denis Wafula, Ph.D., 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) 2298

Notifier: Perstorp AB

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2023.07.14 11:36:39 -04'00'

Attached is the FONSI for FCN 2298, which is for the use of 1,4-Benzenedicarboxylic acid, polymer with 1,2-ethanediol and β,β,β',β',-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol (CAS Reg. No. 102070-64-4) as the basic polymer in the manufacture of films, coatings, and molded articles for single-use and repeated-use food contact applications. 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 (EA), dated May 2, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2023.07.14 11:07:27 -04'00'

Denis Wafula, Ph.D.

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2298, submitted by Perstorp AB for the use of 1,4-Benzenedicarboxylic acid, polymer with 1,2-ethanediol and β,β,β',β',-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol (CAS Reg. No. 102070-64-4) as the basic polymer in the manufacture of films, coatings, and molded articles for single-use and repeated-use food contact applications. The FCS may be used (a) in contact with all food types under Conditions of Use C through G as set forth in Tables 1 and 2, where the spiro glycol content constitutes < 30 mol% total glycol units in the polyester; and (b) in contact with all food types under Conditions of Use B through H as set forth in Tables 1 and 2, where the spiro glycol content constitutes between 30 mol% to 50 mol% total glycol units in the polyester.[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.

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 2, 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 in food-contact materials. Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Disposal of food-contact articles containing the FCS is expected to be through recycling, landfilling, and municipal waste combustors (MWC). No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Because of EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. Further, due to the regulations at 40 CFR Part 60, and others, 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.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below 25,000 metric tons CO_2 equivalent, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

Manufacture of the FCS and its use finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of other cleared alternative polymers (i.e., polyethylene terephthalate and other polyester polymers). Therefore, no net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected. No mitigation measures are needed because no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS. We also do not expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. 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.

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

As evaluated in the EA, the proposed use of the FCS as described in FCN 2298 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2023.07.14 11:07:03 -04'00' Date: see electronic signature

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: 2023.07.14 11:37:24 -04'00' Date: see electronic signature

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