U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: June 26, 2024

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2369

Notifier: GCH Technology Co., Ltd.

To: Stevie Walters, 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: 2024.06.26 13:26:34 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2369, which is for the use of 4-Cyclohexene-1,2-dicarboxylic acid, calcium salt (1:1) (CAS Reg. No. 57545-78-5). The FCS is for use as a nucleating agent in polypropylene homopolymers and copolymers.

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 notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 28, 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.

Antonetta Thompson-wood -S Digitally signed by Antonetta Thompson-wood -S Date: 2024.06.26 13:19:06 -04'00'

Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2369, submitted by GCH Technology Co., Ltd. for the use of4-Cyclohexene-1,2-dicarboxylic acid, calcium salt (1:1) (CAS Reg. No. 57545-78-5). The FCS is for use as a nucleating agent in polypropylene homopolymers and copolymers. The FCS may be used at levels not to exceed 0.2 weight percent in polypropylene homopolymers and copolymers that may contact all food types under Conditions of Use A through H, as described in FDA Tables 1 and 2. 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 March 28, 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.

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, recycling, and combustion rates of food contact articles manufactured with the FCS will correspond with The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Tables and Figures. [1]

Post-consumer disposal of food-contact articles containing the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Due to 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, because of the regulations at 40 CFR Part 60, and others, no significant impacts are expected from incineration of the FCS at MWCs. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

The FCS is expected to be entirely incorporated into finished articles and will remain with the finished food-contact articles throughout the use and disposal. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the finished article manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The EA 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 CO2 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 will consume comparable amounts of energy and resources as similar products already marketed, as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. 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. There is also no impact on current recycling programs.

[1] https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_1010_fnl_508.pdf

No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS, nor do we 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2369 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

Antonetta Thompson-wood -S Digitally signed by Antonetta Thompson-wood -S
Date: 2024.06.26 13:19:57 -04'00'

Antonetta Thompson-Wood, M.S.
Physical Scientist, 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: 2024.06.26 13:27:02 -04'00'

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration