U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 20, 2020

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

To: Laura Dye, Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2075:
Glass-based pearlescent pigments

Notifier: Merck KGaA, Darmstadt, Germany and its affiliated companies

Attached is the FONSI for FCN 2075, which is for the use of glass-based pearlescent pigments as a colorant for food-contact polymers. The 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 July 10, 2020, 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

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2075, submitted by Merck KGaA, Darmstadt, Germany and its affiliates for the use of glass-based pearlescent pigments as a colorant for food-contact polymers. The FCS may be for use at levels up to 5% by weight in polymers in contact with all food types under FDA Conditions of Use A through H and , as described in Tables 1 and 2 (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances , accessed 7/16/20). 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 July 10, 2020. 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 to be used as a colorant for polymers that will be used in food-contact materials. The FCS serves to provide color and pleasing visual appearance to polymeric food-contact articles. Food-contact articles containing the FCS will be utilized in patterns corresponding to population density and will be widely distributed across the country. Disposal will occur nationwide according to rates provided in The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2017 Fact Sheet[1]. Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively and recycled. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. 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. The FCS is a complex matrix of inorganic coated calcium-aluminum-borosilicate glass, formed at high temperatures and contains iron, titanium, and aluminum oxides. The FCS is inorganic and not combustible, and thus, no airborne emission products are expected to be released into the environment upon incineration of food-contact materials which contain the FCS. Therefore, 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, 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 2075 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 07-20-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration

Approved by _____Date: digitally signed 07-20-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
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[1] https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf