U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: September 22, 2020

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

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2082: Glass-based pearlescent pigments

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

Attached is the FONSI for FCN 2082, which is for the use of aluminum oxide (CAS Reg. No. 1344-28-1) as a component of inorganic pigments in combination with other cleared, inorganic substances where the FCS will function as (1) the substrate for the inorganic pigment; and/or (2) a coating component for the inorganic pigment. The inorganic pigment containing the FCS will be used 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, the notifier's environmental assessment (EA), dated August 25, 2020, and the EA Revision Sheet 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

Attachments: Finding of No Significant Impact (FONSI), EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2082, submitted by Merck KGaA, Darmstadt, Germany and its affiliated companies for the use of aluminum oxide (CAS Reg. No. 1344-28-1) as a component of inorganic pigments in combination with other cleared, inorganic substances where the FCS will function as (1) the substrate for the inorganic pigment; and/or (2) a coating component for the inorganic pigment. The inorganic pigment containing the FCS will be used as a colorant for food-contact polymers. Inorganic pigments containing the FCS are intended 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 J, as described in Tables 1 and 2 respectively (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 9/22/20). The finished food-contact articles containing the FCS are 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 August 25, 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 component of inorganic pigments in combination with other cleared, inorganic substances where the FCS will function as (1) the substrate for the inorganic pigment; and/or (2) a coating component for the inorganic pigment. The FCS based pigments serve to provide color and a 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. 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.

[1] https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

As evaluated in the EA, the proposed use of the FCS as described in FCN 2082 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 09-22-2020
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 09-22-2020
Mariellen Pfeil
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U.S. Food and Drug Administration
Revision Sheet for the August 25, 2020 EA for FCN 2082

Dated: September 22, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of August 25, 2020 for food contact notification (FCN) concluded that the action 2082 will not constitute a significant impact. This revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

Page 1 of the EA states
"When the FCS is used as the substrate, the pigments consist of aluminum oxide flakes coated with otherwise-authorized colorant components, such as titanium, iron, tin, and/or silicon oxides. When the FCS is used as a component of inorganic coatings for pigments, it will be deposited onto otherwise-authorized inorganic substrates. The finished pigment containing the FCS is intended for use as a colorant for all food-contact polymers, for use at up to 5% by weight in the polymers."

To reflect the final regulatory language for the notification, this should instead state:
"The inorganic pigment containing the FCS will be used as a colorant for food-contact polymers. The FCS may also be used as metal oxide coating component of inorganic pigments that will be used as colorants for food-contact polymers. Inorganic pigments containing the FCS are intended for use at levels up to 5% by weight in polymers."