
Memorandum

Date: February 22, 2021

To: Jacqueline Heilman, Ph.D. 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) 2119:
Tin (IV) oxide (CAS Reg. No. 18282-10-5)

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

Attached is the FONSI for FCN 2119, which is for the use of Tin (IV) oxide (CAS Reg. No. 18282-10-5) for use in combination with titanium dioxide as a component of inorganic pigments. The pigment containing the FCS will be used as a colorant for food-contact polymers, coatings, paper and paperboard and in printing inks applied to non-food-contact surfaces of food-contact articles. 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 December 23, 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

Attachment:

FONSI

EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Notification (FCN) 2119, submitted by Merck KGaA, Darmstadt, Germany and its affiliated companies for the use of tin (IV) oxide (CAS Reg. No. 18282-10-5) for use in combination with titanium dioxide as a component of inorganic pigments. The pigment containing the FCS will be used as a colorant for food-contact polymers, coatings, paper and paperboard and in printing inks applied to non-food-contact surfaces of food-contact articles. The FCS is for use at levels up to 12% of the total inorganic pigment weight. The finished food-contact articles containing the FCS may contact all food types under 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 2/16/21).

The FCS is not intended 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 December 23, 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 in combination with titanium dioxide as a colorant for food-contact polymers, coatings, paper and paperboard, and in printing inks to non-food-contact surfaces of food-contact articles at levels up to 12% by weight of the colorant. The FCS converts the titanium dioxide to a rutile structure, with the final pigments acting to provide color and a pleasing visual appearance to food-contact articles. The food-contact articles include food packaging and repeat-use articles, as well as disposable food-contact materials such as utensils and serving ware. 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: 2017 Fact Sheet¹. 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. 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.

The FCS is inorganic and not combustible; thus, no airborne emission products are expected to be released into the environment as a result of the incineration of the materials manufactured with the FCS. Since the FCS does not contain constituents that may generate greenhouse gases (GHGs), when incinerated at municipal solid waste combustion facilities, no GHG analysis was provided. Therefore, no significant environmental impacts are anticipated.

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
www.fda.gov

As evaluated in the EA, the proposed use of the FCS as described in FCN 2119 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 02-22-2021

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 02-22-2021

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

U.S. Food and Drug Administration Revision Sheet for the December 23, 2020 EA for FCN 2119

Revision Sheet Dated: February 22, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated December 23, 2020 for food contact notification (FCN) 2119 concluded that the action 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:

In Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA (see the below links).

https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf

https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

We note that this update does not impact the conclusions presented in the EA, so no revision is required. However, the reader is advised to refer to these reports.