U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 15, 2023

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

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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) 2279: n-Octyl phosphonic acid (NOPA)-modified titanium dioxide, (produced by chemically reacting NOPA (CAS Reg. No.4724-48-5) with titanium dioxide to achieve a treatment level of 0.85% by weight of NOPA on the pigment)

Notifier: Cinkarna Celje

Attached is the FONSI for FCN 2279, which is for the use of n-Octyl phosphonic acid (NOPA)-modified titanium dioxide, (produced by chemically reacting NOPA (CAS Reg. No.4724-48-5) with titanium dioxide to achieve a treatment level of 0.85% by weight of NOPA on the pigment) as a colorant in food-contact polymers. 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 direct-edited environmental assessment (EA), dated February 17, 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.

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Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2279 is submitted by Cinkarna Celje for the use of n-Octyl phosphonic acid (NOPA)-modified titanium dioxide, (produced by chemically reacting NOPA (CAS Reg. No.4724-48-5) with titanium dioxide to achieve a treatment level of 0.85% by weight of NOPA on the pigment) as a colorant in food-contact polymers. The FCS is for use at a maximum level of 20 percent by weight of finished polymers in contact with all food types under Conditions of Use (COU) A, B, and H; and a maximum use level of 30 percent by weight of finished polymers that are used in contact with all food types under COU C-G. Use of the colorant is subject to the provisions and definitions set forth in 21 CFR 178.3297. 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 a direct-edited environmental assessment (EA), dated February 17, 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 finished 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, 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 Fact Sheet[1]. Post-consumer disposal of food-contact articles containing the FCS will be to landfills and 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. Further, because of 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 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 and its use finished food-contact articles will consume energy and resources in amounts comparable to similar substances on the market (i.e., NOPA-modified TiO2 that is the subject of effective FCNs 38 and 419, for which the FCS will serve as a substitute). 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 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.

[1] https://www.epa.gov/sites/production/files/2021-11/documents/2018_ff_fact_sheet.pdf

As evaluated in the EA, the proposed use of the FCS as described in FCN 2279 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
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