U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: August 11, 2021

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2164: Niobium-doped titanium dioxide, coated with calcium titanate (CAS Reg. 2662012-00-1 and 12049-50-2, respectively).

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

To: Vivian Gilliam, 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: 2021.08.11 16:16:23 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2164, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2164 is for the use of niobium-doped titanium dioxide, coated with calcium titanate for use as a laser-marking agent to assist in providing dark markings on food-contact polymers at a maximum concentration of 0.5 percent by weight in polymers. This FCS may be used in contact with all types of foods under Conditions of Use A through H, as described in Tables 1 and 2[1], in both single- and repeat-use articles, but not in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated June 7, 2021 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.

Brittany Ott -S Digitally signed by Brittany Ott - S Date: 2021.08.11 16:13:05-04'00'

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Attachment: Finding of No Significant Impact (FONSI)

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2164, submitted Merck KGaA, Darmstadt, Germany, and its affiliated companies for the use of niobium-doped titanium dioxide, coated with calcium titanate, as a laser-marking agent intended for use in all food-contact polymers, except for use in contact with infant formula and human milk, as specified below.

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 June 7, 2021. 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 as a laser-marking agent, as the FCS pigments are conductive, transparent oxide (CTO) laser additives that assist in providing dark markings on food packaging polymers, which allow for useful product information to be more easily shown on packaging and/or to convey a pleasing visual appearance to the finished material. The FCS is for use in contact with all types of food under Conditions of Use A through H. The maximum concentration will be 0.5 percent by weight of the polymer, and the resultant food-contact articles may include food packaging and repeat-use articles. The FCS will not be for use in contact with infant formula and human milk, and as such these uses were not included as part of the intended use of the substance in the FCN.

The notifier does not intend to produce finished food-contact articles using the FCS; rather, the FCS will be sold to food-contact article manufacturers and will be entirely incorporated into finished food-contact articles. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.[2] Post-consumer disposal of food-contact articles containing the FCS will be by recycling, or to landfills and municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. EPA's regulations governing landfills at 40 CFR Part 258, preclude leaching into the environment from food-contact articles manufactured with the FCS. Additionally, the FCS does not readily migrate from the finished food-contact article. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, 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 as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. 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.

[2] We note that in Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA. Please see the following 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 report does not impact the conclusions presented in the EA, so no revision was required. However, the notifier was advised to utilize these reports in their future submissions.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2164 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Brittany Ott -S Digitally signed by Brittany Ott -S Date: 2021.08.11 16:13:33 -04'00' Date: see electronic signature

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Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2021.08.11 16:17:13 -04'00' Date: see electronic signature

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