FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: October 20, 2022

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2252: Titanium nitride (CAS Reg. No. 25583-20-4)

Notifier: Avient Corporation and its stewarded global affiliates

To: Vanee Komolprasert, 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: 2022.10.20 14:05:03 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2252, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2252 is for the use of titanium nitride as an additive in food-contact polyethylene terephthalate (PET) materials, intended to contact food all food types under Conditions of Use A through H, and J, as described in Table 2[1], except for use in contact with infant formula and human milk. The FCS is for use at levels up to 25 parts per million (ppm) (w/w) in finished PET materials.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated September 12, 2022 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)

[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) 2252, submitted by Avient Corporation and its stewarded global affiliates for the use of titanium nitride as an additive in food-contact polyethylene terephthalate (PET) materials, except for 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 September 12, 2022. 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, titanium nitride, is intended for use as an additive in food-contact polyethylene terephthalate (PET) materials in contact food all food types under Conditions of Use A through H, and J, as described in Table 2[2], except for use in contact with infant formula and human milk. The FCS is for use at levels up to 25 parts per million (ppm) (w/w) in finished PET materials. The FCS is expected to be entirely incorporated into and remain with the finished food-contact article and any waste materials generated in the process, e.g. plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration) and recycling.

The National Association for PET Container Resources (NAPCOR) estimates that 28% of PET bottles were recycled in 2019[3]. ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made[4]. It is therefore anticipated that the PET manufactured containing the FCS would be so marked and thus coded for identification as PET. Additionally, 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*. Thus, we expect post-consumer disposal of food-contact articles containing the FCS that are not recycled will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively.

Finally, as the FCS is an inorganic compound that melts at approximately 2950°C, the FCS is not expected to readily volatilize and/or combust. Also, virtually no leaching to the environment is expected under normal environmental conditions when disposed of in sanitary landfills. 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

[2] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances
[3] See National Association for PET Container Resources (NAPCOR), NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow, available at: https://napcor.com/news/4970-2/
[4] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20

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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2252 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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Approved by

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