U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 24, 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) 2212: Tin antimony gray cassiterite (CAS Reg. No. 68187-54-2 and CAS Reg. No. 12673-86-8).

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

To: Vivian Gilliam, 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: 2022.03.24 14:33:16 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2212, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2212 is for the use of tin antimony gray cassiterite as a laser-marking agent for all food-contact polymers, except for you in contact with infant formula and human milk. The FCS will be used at levels up to: 0.5% by weight in polymers in contact with all food types under Conditions of Use E through G, as described in Tables 1 and 2[1], respectively; and 0.1% by weight in polymers in contact with all food types under Conditions of Use C through D, as described in Tables 1 and 2, respectively. The FCS is not for use in contact with infant formula and human milk, and such uses are not included as part of the intended use of the substance in the FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated February 22, 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.

Brittany Ott -S Digitally signed by Brittany Ott -S Date: 2022.03.24 14:26:58 -04'00'

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI)

cc: HFS-255 Ott
File: FCN No. 2212

[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) 2212, submitted by Merck KGaA, Darmstadt, Germany and its affiliated companies for the use of tin antimony gray cassiterite as a laser-marking agent for 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 February 22, 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 is intended for use as a nucleating agent in the manufacture of polyolefin food contact materials and articles, for single and repeated-use applications. The FCS will be used at levels up to: 0.5% by weight in polymers in contact with all food types under Conditions of Use E through G, as described in Tables 1 and 2[2], respectively; and 0.1% by weight in polymers in contact with all food types under Conditions of Use C through D, as described in Tables 1 and 2, respectively. The FCS will be entirely incorporated into the finished food article and will be sold to manufacturers engaged in the production of the finished food contact articles. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration).

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*. Post-consumer disposal of food-contact articles containing the FCS will be by recycling, landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The FCS is an inorganic, non-combustible, water-insoluble antimony doped crystal structure that contains antimony interdiffused in place of various tin (Sn) sites within a tin dioxide cassiterite lattice. As such, there is nothing to suggest that the FCS would be in violation of 40 CFR 60 and 62, which address combustion emissions, and data regarding the production of GHG emissions from this FCS is not required.

Finally, due to the nature (inorganic, non-combustible, water-insoluble) and use (expected to be entirely incorporated into the finished food-contact material), no significant exposures to air, water, or land environments are anticipated. 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2212 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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

Brittany Ott -S Digitally signed by Brittany Ott -S
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Prepared by _____ Date: see electronic signature

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