U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: June 16, 2022

To: Jessica Urbelis, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.06.16 12:04:47 -04'00'

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) 2213: Oleic acid, mono ester with oxybis(propanediol) (CAS Reg. No. 49553-76-6)

Notifier: DuPont Nutrition & Biosciences ApS

Attached is the FONSI for FCN 2213, which is for the use of oleic acid, mono ester with oxybis(propanediol) (CAS. Reg. No. 49553-76-6) as an antistatic agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers intended to contact food, including infant formula and human milk. 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, the notifier's environmental assessment (EA), dated February 24, 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.

Antonetta Thompson-wood -S Digitally signed by Antonetta Thompson-wood -S Date: 2022.06.16 11:36:58 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2213, submitted by DuPont Nutrition & Biosciences ApS for the use of oleic acid, mono ester with oxybis(propanediol) (CAS. Reg. No. 49553-76-6) as an antistatic agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers, intended to contact food. The FCS is for at levels up to 350 parts per million (ppm) in polypropylene and polyethylene homopolymers and copolymers, in contact with all food types under Conditions of Use A through H and J, as described in FDA Table 2(https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 6/16/22).
The FCS may be used in films and articles intended to contact infant formula and human milk.

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 24, 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 an antistatic agent in the polymerization process to produce food contact plastics (polypropylene and polyethylene). The FCS improves the yield from the polymerization process and results in increased throughput rates. 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-e, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles with or without antistatic agents. 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/default/files/2020-11/documents/2018_ff_fact_sheet.pdf

As evaluated in the EA, the proposed use of the FCS as described in FCN 2213 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Antonetta Thompson-wood -S Digitally signed by Antonetta Thompson-wood -S Date: 2022.06.16 11:37:49 -04'00' Date: see electronic signature

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 Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.06.16 12:06:26 -04'00' Date: see electronic signature

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