Memorandum

Date: March 4, 2020

To: Jessica Urbelis, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Leah Proffitt, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

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) 2037: Oleic acid, mono ester with oxybis (propanediol) (also known as diglyceryl monooleate) (CAS Reg. No. 49553-76-6)

Notifier: DuPont Nutrition & Biosciences ApS and DuPont de Nemours, Inc.

Attached is the FONSI for FCN 2037, which is for the use of oleic acid, mono ester with oxybis (propanediol) as an antistatic agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers intended to contact food, including infant formula and human milk. The 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 environmental assessment (EA), dated January 31, 2020, 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

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2037, submitted by DuPont Nutrition & Biosciences ApS and DuPont de Nemours, Inc. 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. The FCS may be for use at levels up to 50 parts per million (ppm) in polypropylene homopolymers and copolymers, and at levels up to 350 ppm in polyethylene homopolymers and copolymers in contact with all food types under Conditions of Use A through H, and J, as described in FDA Tables 1 and 2 (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 2/18/20). The FCS may be used in 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 January 31, 2020. 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 manufacture of polypropylene and polyethylene homopolymers and copolymers intended to contact food, including infant formula and human milk. 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. Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively and recycled. Because the FCS is used at an exceedingly low level in the manufacture of polyolefins, there will be no significant impact on current or future recycling programs. 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. According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO2-equivalent (CO2-e) in metric tons (mT), are well below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, 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, 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2037 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 03-04-2020

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 _____Date: digitally signed 03-04-2020
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