

Memorandum

Date: August 30, 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) 2244: Oleic acid, mono ester with oxybis(propanediol) (CAS Reg. No. 49553-76-6)

Notifier: Palsgaard A/S

To: Kenneth McAdams, 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

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2244, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2244 is for the use of oleic acid, mono ester with oxybis(propanediol) as an antistatic/antifouling agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers intended to contact food all food types under Conditions of Use A through J, as described in Table 2¹, including infant formula and human milk. The FCS is for use at levels up to 100 parts per million (ppm) in polypropylene homopolymers and copolymers, and at levels up to 350 ppm in polyethylene homopolymers and copolymers.

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

Digitally signed by Brittany Ott

Brittany Ott -S

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Brittany Ott

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) 2244, submitted by Palsgaard A/S for the use oleic acid, mono ester with oxybis(propanediol) as an antistatic/antifouling agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers, including 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 July 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 of oleic acid, mono ester with oxybis(propanediol) as an antistatic/antifouling agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers intended to contact food all food types under Conditions of Use A through J, as described in Table 2², including infant formula and human milk. The FCS is for use at levels up to 100 parts per million (ppm) in polypropylene homopolymers and copolymers, and at levels up to 350 ppm in polyethylene homopolymers and copolymers. The FCS is expected to be entirely incorporated into and remain with the finished food-contact article and will be sold to manufacturers engaged in the production of the finished food contact articles.

Any waste materials generated in the process of producing the pads is 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.

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 landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected carbon dioxide equivalent emissions are below the 25,000 metric ton EPA reporting threshold.

Finally, due to minimal migration of the FCS polymer components and the fact that the FCS does not volatilize during use, virtually no leaching is expected and is therefore expected to remain with 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 <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

As evaluated in the EA, the proposed use of the FCS as described in FCN 2244 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
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Brittany Ott, Ph.D.
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Approved by **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S
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