

## Memorandum

**Date:** November 15, 2019

**To:** Elizabeth S. Furukawa, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)

**Through:** Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety, HFS-255

**From:** Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2005: Trimethylolpropane trisorbate (TMPTS) (CAS Reg. No. 2307636-51-5)).

**Notifier:** Milliken Chemical

Attached is the FONSI for FCN 2005, which is for the use of trimethylolpropane trisorbate for use as a grafting agent in the manufacture of impact-modified polypropylene.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated September 13, 2019, 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) 2005, submitted by Milliken Chemical for the use of trimethylolpropane trisorbate (TMPTS) for use as a grafting agent in the manufacture of impact-modified polypropylene. The FCS will be used at levels not to exceed 0.4 percent by weight of finished impact-modified polypropylene. The FCS may be used in contact with all food types under Conditions of Use C through G, 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 10/24/19). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

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 13, 2019. 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 grafting agent in the manufacture of impact-modified polypropylene. 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, or recycled. 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 CO<sub>2</sub>-equivalent (CO<sub>2</sub>-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 municipal solid waste (MSW) combustion facilities. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy as finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of other polypropylene additives. No mitigation measures are needed since no significant impacts are expected from use of the FCS. 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 environment.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2005 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by \_\_\_\_\_ Date: digitally signed 11-15-2019

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Approved by \_\_\_\_\_ Date: digitally signed 11-15-2019

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