Memorandum

Date: May 23, 2019

To: Anita Chang, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
Through: Leah Proffitt, Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1988: Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-tert-butylphenyl) ester (CAS Reg. No. 26741-53-7) for use as an antioxidant in polyprophylene homopolymers and copolymers that contact food.

Notifier: Addivant

Attached is the FONSI for FCN 1988.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated May 7, 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

A food-contact notification (FCN) 1988, submitted by Addivant for the use of phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-tert-butylphenyl) ester (CAS Reg. No. 26741-53-7) as an antioxidant in polypropylene homopolymers and copolymers that contact food. The FCS shall be used at levels up to 750 parts per million (0.075 percent) by weight of polypropylene homopolymers and copolymers that contacts food under FDA Conditions of Use A. The FCS may be used in conjunction with triisopropanolamine (CAS Reg. No. 122-20-3) at a maximum use level of 1 percent by weight of the FCS. The FCS is not for use in contact with infant formula and human milk.

The Office of Food Additive Safety has determined that allowing FCN 1988 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 May 7, 2019. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Impacts to the Environment as a Result of Use and Disposal

The FCS is intended for use as an antioxidant at levels up to 750 parts per million by weight in polypropylene homopolymers and copolymers that contact food under FDA Conditions of Use A. The FCS will be used in conjunction with triisopropanolamine (TIPA; CAS Reg. No. 122-20-3) at a maximum use level of 1 percent by weight of the FCS. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or municipal solid waste (MSW) combustors 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. Based on an analysis using consumption factor information, incineration at permitted MSW combustion facilities of items containing the FCS is not expected to exceed the 25,000 mT reporting requirement specified at 40 CFR 98.2. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy. 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 currently approved processing aids; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 1988 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 05/23/2019
Antonetta Thompson-Wood
Physical Scientist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 05/23/2019
Leah Proffitt
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