Memorandum

Date: February 20, 2019

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

From: Physical Scientist, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1927: Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (CAS Reg. No. 939402-02-5) for use as an antioxidant in styrene block polymers and repeat use elastomers, including use in contact with infant formula and human milk.

Notifier: Addivant

Attached is the FONSI for FCN 1927.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated October 29, 2018, 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) 1927, submitted by Addivant for the use of Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl) phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (CAS Reg. No. 939402-02-5) for use as an antioxidant in styrene block polymers and repeat use elastomers. The FCS may be used at levels up to 0.5 percent by weight in styrene block polymers and repeat elastomers for use in contact with all food types under FDA Conditions of Use A through H. The FCS may be used in styrene block polymers authorized for use as packaging for powdered infant formula, as well as in styrene block polymers and elastomers authorized for use in repeat use articles in contact with infant formula and human milk. The FCS may be used in conjunction with triisopropanolamine (CAS Re. No 122-20-3) at a maximum use level of 0.75 percent by weight of the FCS.

The Office of Food Additive Safety has determined that allowing FCN 1927 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 October 29, 2018. 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 in styrene block polymers in polymeric food-contact materials. The FCS inhibits oxidation, and thus deterioration of technical performance, of polymers used in food-contact materials. 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. Finished food-contact materials containing the FCS are not expected to be recycled because styrene block polymers (e.g., styrene-butadiene-styrene polymers and styrene-isoprene-styrene polymers, etc.), and repeat use elastomers are not the subject of widespread recycling programs within the United States. Moreover, food-contact articles that are expected to be manufactured from the materials described in the current Notification are not typically recycled and are instead removed from the recycling stream based on source control procedures. [1] Articles containing the FCS are expected to be removed from the recycling process stream using such source control procedures, if they inadvertently entered the stream. 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. The FCS is comprised of carbon, hydrogen, oxygen, and phosphorus, and will not significantly alter the emissions from properly operating MSW combustion facilities as these elements are commonly found in MSW. Further, incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60, regulations for mandatory emissions reporting at 40 CFR Part 98, and/or other relevant state and local laws. Based upon an analysis using market volume information there are no significant impacts with respect to greenhouse gas emissions resulting from food-contact articles manufactured with the FCS.

Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of Resources and Energy

The FCS will replace similar articles now on the market for use in food-contact articles. Use of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact substances. The manufacturer of the FCS will consume comparable amounts of energy and resources as similar products already being marketed (i.e., antioxidants permitted for use in styrene block polymers and/or repeat use elastomers under 21 C.F.R. Section 178.2010), as the raw materials used in the production of the FCS are commercially manufactured materials that

[1] See: The Association of Plastic Recyclers, "Near Infrared (NIR) Sorting in the Plastics Recycling Process," at: https://www.plasticsrecycling.org/images/pdf/designguide/Resources/NIR_Sorting_Resource.pdf, discussing the processes for sorting different types of resin that may enter the recycle stream

are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles manufactured from the FCS. Therefore, mitigation measures are not required.

Alternatives to the Proposed Action

No significant adverse environmental effects were identified in the EA that would necessitate alternative actions for the proposed use in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the articles that the FCS would replace. Such action would have no significant environmental impacts.

As evaluated in the EA, the proposed use of the FCS as described in FCN 1927 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed on 02-20-2019
Antonetta Thompson-Wood
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed on 02-20-2019
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