U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 24, 2020

To: Vanee Komolprasert, 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)

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2076: Tris(2,4-di-*tert*-butylphenyl)phosphite (CAS Reg. No. 31570-04-4)

Notifier: BASF Corporation

Attached is the FONSI for FCN 2076, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2076 is for the use of Tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant/stabilizer in styrene block copolymers for use as a component of food-contact articles, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's EA, dated July 15, 2020, may be made available to the public. We will post digital transcriptions of the FONSI, the EA revision sheet 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.

Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2076, submitted by BASF Corporation for the use Tris(2,4-di-tert-butylphenyl)phosphite (CAS Reg. No. 31570-04-4) as an antioxidant/stabilizer in styrene block copolymers for use as a component of food-contact articles. The FCS is intended to be used at levels not to exceed 0.4 percent by weight of styrene block copolymers for contact with all food types under Conditions of Use A through H described in Tables 1 and 2. (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 7/21/2020). The FCS is not intended 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 July 15, 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 antioxidant/stabilizer in styrene block copolymers for use as a component of food-contact articles. The notifier will not fabricate any food-contact articles but intends to market the FCS to other manufacturers engaged in the production of food-contact articles. 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 waste combustors (MWC) 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. Per information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO_2-equivalent (CO_2-e) in metric tons (mT), will not exceed 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 MWC facilities. 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 the continued use of currently approved substances that that the FCS would have replaced. Such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2076 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 07-24-2020
Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 07-24-2020
Mariellen Pfeil
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Food and Drug Administration

U.S. Food and Drug Administration
Revision Sheet for the July 15, 2020 EA for FCN 2076

July 24, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of July 15, 2020 for food contact notification (FCN) 2076 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary provide information that is missing in the EA:

Under Item 6.c (Introduction of Substances into the Environment as a Result of Use/Disposal), phosphorous should also be included as a component of the FCS.