Memorandum

Date: December 10, 2018

To: Elizabeth Furukawa, Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Supervisory Biologist, Office of Food Additive Safety, HFS-255

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1935 for Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate; CAS Reg. No. 2082-79-3; a.k.a. Irganox 1076.

Notifier: TSRC Corporation

Attached is the Finding of No Significant Impact (FONSI) for FCN 1935 for Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate; CAS Reg. No. 2082-79-3, as an antioxidant in styrene block polymers with 1,3-butadiene, hydrogenated (SEBS, CAS Reg. No. 66070-58-4), except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated October 23, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1935), submitted by TSRC Corporation, to provide for the safe use of Octadecyl 3,5-di-tert-butyl-4- hydroxyhydrocinnamate; CAS Reg. No. 2082-79-3, as an antioxidant in styrene block polymers with 1,3-butadiene, hydrogenated (SEBS, CAS Reg. No. 66070- 58-4), except for use in contact with infant formula and human milk. The FCS may be used at levels not to exceed 0.07 percent by weight of SEBS authorized for the same use. Articles containing the FCS may contact food types I, II, IV-B, VI, VII-B, and VIII under conditions of use A through H.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated October 23, 2018. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Items containing the FCS are expected to be land disposed or combusted proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: Facts and Figures 2015." Items manufactured with the FCS are expected to be recycled in proportion to national figures reflected in the EPA report. Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. Market volume information provided in a confidential attachment to the EA demonstrates that the FCS will comprise a very small portion of MSW, compared to overall MSW generated; this comparison uses EPA's 2015 MSW statistics.

According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO2-equivalent (CO2-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 MSW combustion facilities.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials currently used.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no environmental impact.

Consequently, we find that use of the FCS as as a polymeric component of food-contact articles as described in FCN 1935, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 12-10-2018
Leah D. Proffitt
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed
12-10-2018 Mariellen Pfeil
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