Date: June 2, 2020

To: Kenneth McAdams, Division of Food Contact Substances (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) 2051 for bis (4-tert-butylbenzoate-O) hydroxyl aluminum (CAS Reg. No. 13170-05-3).

Notifier: Shanghai Xinxin Chemical Co., Ltd.

Attached is the FONSI for FCN 2051 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2051 is for the use of bis (4-tert-butylbenzoate-O) hydroxyl aluminum as an additive to increase rigidity and impact modulus in polypropylene homopolymer and high propylene olefin copolymers, at a level not to exceed 0.1 percent by weight of the finished polymer.

After this FCN becomes effective, copies of this FONSI, EA Supplement and the notifier's environmental assessment (EA), dated April 25 may be made available to the public. We will post digital transcriptions of the FONSI, EA Supplement 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

Attachments: Finding of No Significant Impact
Supplement to the April 25, 2020 Environmental Assessment for FCN 2051

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2051: submitted by Shanghai Xinxin Chemical Co., Ltd., for the safe use of bis (4-tert-butylbenzoate-O) hydroxyl aluminum as an additive to increase rigidity and impact modulus in polypropylene homopolymer and high propylene olefin copolymers, at a level not to exceed 0.1 percent by weight of the finished polymer. The finished polymers may be used in the form of molded articles in contact with all types of food under Conditions of Use A through H as described in Table 2.

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 April 25, 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 and is briefly summarized below.

Items manufactured with 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 2016 and 2017." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Since these items will not be recycled, they will not interfere with recycling patterns. 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.

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 already in use.

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 significant environmental impact.

Consequently, we find that use of the FCS for use in in polypropylene homopolymer and high propylene olefin copolymers as described in FCN 2051, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

An EA supplement has been prepared and attached to this FONSI to support the assertion of no significant impacts from greenhouse gases due to combustion of articles containing the FCS in municipal solid waste combustion facilities.

Prepared by _____Date: digitally signed 06-02-2020
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 06-02-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety

Center for Food Safety and Applied Nutrition
Food and Drug Administration
Attachment: Supplement to the Environmental Record for FCN 2051

U.S. Food and Drug Administration
Supplement to the April 25, 2020 EA for FCN 2051

This document incorporates by reference the notifier's environmental assessment (EA), dated April 25, 2020.

The purpose of this supplement is to ensure the accuracy and completeness of the environmental record and to assist the public in understanding the agency's basis for preparing a finding of no significant impact (FONSI).
The approval of the action poses a potential environmental impact from the emission of greenhouse gases. The EA adequately addresses the finding that emissions resulting from incineration of articles containing the FCS in municipal solid waste combustion facilities do not pose a significant environmental impact. However, a quantitative analysis to support this finding was lacking. We provide this analysis using publicly available data in this EA supplement.

We consulted the data from EPA's 2016/2017 Municipal Solid Waste (MSW) report, and the notifier's chemical identity information.

Chemical identity[1]:
$C_{22}H_{28}AlO_5$
399.4 g/Mol
percent carbon: 66.15

We assume conservatively that the FCS will be used in all "Óther plastic containers" that were combusted with energy recovery in 2016, i.e. 320,000 short tons (= 288,000 mT; see Table 8A from EPA's 2016-2017 Advancing Sustainable Materials Management Report)[2]. Of that amount, only 0.1% (FCS use level; 0.01) contains the actual FCS, or 2,880 mT. This is assumed to be the market volume, which we multiply by the percent carbon (0.66) to estimate the mT of carbon combusted (=1,900.8 mT). Entering this amount into EPA's Greenhouse Gas Equivalencies Calculator[3] yields a CO_2 equivalent (CO_2-e) amount of 6,967 mt CO_2-e. This amount is below the 25,000 mT reporting threshold for any single MSW combustion facility described in 40 CFR 98.2.

Thus, there are no significant environmental impacts identified resulting from the notified use of this FCS.

Prepared by: _____ Date: digitally signed 06-02-2020
Leah D. Proffitt
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[1] https://www.lenntech.com/calculators/molecular/molecular-weight-calculator.htm
[2] https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report
[3] https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator