Memorandum

Date: February 4, 2020

To: Kelly Randolph, DVM, MPH, Division of Food Contact Substances, HFS-275
Through: Antonetta Thompson-Wood, MS, Physical Scientist, 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) 2027 for silicic acid, aluminum magnesium sodium salt (CAS Reg. No. 12040-43-6).

Notifier: W. R. Grace & Co.-Conn.

Attached is the FONSI for FCN 2027 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2027 is for the use of silicic acid, aluminum magnesium sodium salt (CAS Reg. No. 12040-43-6) as an acid scavenger in polypropylene (PP), at levels up to 600 parts per million (ppm) by weight.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated January 8, 2020, 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

Food Contact Substance (FCS) Notification (FCN) 2027: submitted by W. R. Grace & Co.-Conn., for the safe use of silicic acid, aluminum magnesium sodium salt (CAS Reg. No. 12040-43-6) as an acid scavenger in polypropylene (PP), at levels up to 600 parts per million (ppm) by weight. The FCS may contact all food types under Conditions of Use A through H, as described in FDA Tables 1 and 2 (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 2/3/2020). The FCS is not for use in contact with infant formula and human milk.

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 January 8, 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 2015." 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.

The FCS does not contain elements that may generate greenhouse gases (GHG) (e.g. carbon, nitrogen, fluorine). Therefore, no GHG emissions are expected to form during incineration of discarded items containing the FCS.

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 as an acid scavenger in PP as described in FCN 2027, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 02-04-2020
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 02-04-2020
Antonetta Thompson-Wood
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