Memorandum

Date: November 24, 2020

To: Vivian Gilliam Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2108:
Silicic acid, aluminum magnesium sodium salt (CAS Reg. No. 12040-43-6) as an acid scavenger in polypropylene (PP), at levels up to 1800 parts per million (ppm) by weight.

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

Attached is the FONSI for FCN 2108, which is for the use of silicic acid, aluminum magnesium sodium salt (CAS Reg. No. 12040-43-6) as an acid scavenger in PP, at levels up to 1800 ppm by weight, except for use with infant formula and human milk. The FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

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

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2108, submitted by W. R. Grace & Co.-Conn. 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 1800 parts per million (ppm) by weight. The FCS is for use in contact under Conditions of Use A through H and J as described in Tables 1 and 2 respectively (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 11/24/20).

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 October 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 (FONSI) and is briefly summarized below.

The FCS is intended to be used as an acid scavenger in PP, at levels up to 1800 ppm by weight. The FCS is used as a component of finished food contact articles. The FCS passivates the residual catalyst used in the manufacture of PP and protects the finished article. The food contact articles include food packaging and repeat-use articles, as well as articles such as utensils, plastic cups and plastic plates. Food-contact articles containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Disposal, recycling and combustion rates of food contact articles manufactured with the FCS will correspond with The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2017 Fact Sheet.[1] Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. Food-contact materials manufactured with the FCS will not be recycled. 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. Therefore, no significant impacts are expected from incineration of the FCS at MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

The FCS is not combustible; thus, no airborne emission products are expected to be released into the environment as a result of the incineration of the materials manufactured with the FCS. Since the FCS does not contain constituents that may generate greenhouse gases (GHGs), when incinerated at municipal solid waste combustion facilities, no GHG analysis was provided. Therefore, no significant environmental impacts are anticipated.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

[1] https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

As evaluated in the EA, the proposed use of the FCS as described in FCN 2108 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 11-24-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-08-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
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U.S. Food and Drug Administration
Revision Sheet for the October 8, 2020 EA for FCN 2108

Revision Sheet Dated: November 24, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated October 8, 2020 for food contact notification (FCN) 2108 concluded that the action will not constitute a significant impact. This revision is issued to make a minor change and update of an editorial nature 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 to explain the following:

- Page 3 of the EA states:
  "EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection system, they are required to monitor groundwater and to take corrective action as appropriate. There is no migration of the FCS from polymers in which it is used. Therefore, there is no expectation that the FCS will enter the environment."

  A portion of this statement is not applicable to the current notification as it pertains to landfill operations which ceased receiving wastes in 1993. Therefore, this paragraph statement should state:

  "EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water. There is no migration of the FCS from polymers in which it is used. Therefore, there is no expectation that the FCS will enter the environment."

- Page 4 of the EA states:
  "…FCS as proposed is not expected to result in significant impact to the environment."

  This should state:
  "…FCS as proposed is not expected to result in significant impact to the environment. Therefore, the FCS is not expected to result in environmental issues requiring mitigation measures."