

Memorandum

Date: February 14, 2022

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2211: Calcium tert-butylphosphonate (CAS Reg. No 81607-35-4).

Notifier: Milliken Chemical, Division of Milliken & Co.

To: Huichen Chang, 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)

Mariellen Pfeil -S

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Date: 2022.02.14 16:41:23 -05'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2211, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2211 is for the use of Calcium tert-butylphosphonate as a nucleating agent in the manufacture of polyolefin food contact materials and articles, for single and repeated-use applications. The FCS will be used at a maximum level of 0.15 weight percent in polyolefins in contact with all food types under Conditions of Use A through H¹, and J (microwave only, excluding susceptor applications). The FCS may be used in articles intended to contact infant formula and human milk.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated December 6, 2021 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.

Brittany Ott -S Digitally signed by Brittany Ott -S
Date: 2022.02.14 16:23:21 -05'00'

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI)

cc: HFS-255 Ott
File: FCN No. 2211

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2211, submitted by Milliken Chemical, Division of Milliken & Co., for the use Calcium tert-butylphosphonate, as a nucleating agent in the manufacture of polyolefin food contact materials and articles, for single and repeated-use applications, including for use in contact with infant formula and human milk, as specified below.

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 December 6, 2021. 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 a nucleating agent in the manufacture of polyolefin food contact materials and articles, for single and repeated-use applications. The FCS will be used at a maximum level of 0.15 weight percent in polyolefins in contact with all food types under Conditions of Use A through H, and J (microwave only, excluding susceptor applications). The FCS will be entirely incorporated into the finished food article and will be sold to manufacturers engaged in the production of the finished food contact articles, to include food packaging and repeat-use articles, as well as utensils, plastic cups, and plastic plates. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration).

Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*. Post-consumer disposal of food-contact articles containing the FCS will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Articles manufactured with the FCS are not expected to be recycled. EPA's regulations governing landfills at 40 CFR Part 258, preclude leaching into the environment from food-contact articles manufactured with the FCS. Additionally, a full assessment of green house gas (GHG) emissions is provided in a confidential attachment to the EA. Based on estimated market volume information provided in a confidential attachment to the EA, the total annual emissions of the greenhouse gases (GHG) resulting from combustion of items manufactured with the FCS are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2.²

Finally, "minute" levels of leaching of potential migrants (0.008 – 0.010 ppm depending on the solvent) from the finished food article indicate that there will be no significant adverse environmental impacts expected. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, 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.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. 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.

² This statement is supported by data contained in a Confidential Attachment provided by the notifier in conjunction with the EA.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2211 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Brittany Ott -S** Digitally signed by Brittany Ott -S
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Office of Food Additive Safety
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Approved by **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S
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