U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: January 7, 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) 2191: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and 4-hydroxybutyl acrylate, acetates (salts) (CAS Reg. No. 2374117-56-1).

Notifier: Daikin America, Inc.

To: Sharon Koh-Fallet, 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 Digitally signed by Mariellen Pfeil -S Date: 2022.01.07 17:20:35 -05'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2191, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2191 is for the use of 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and 4-hydroxybutyl acrylate, acetates (salts) to impart grease and oil resistance to paper and paperboard, added at the size press, with a maximum application rate of 0.6 g/m^2 of the dry paper and paperboard. It is intended for use in paper and paperboard that may contact all types of food under Conditions of Use A through H[1]. However, the FCS is not intended for use in contact with infant formula and human milk, and as such, these uses were not included as part of the intended use of the substance in the FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated October 1, 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: 2022.01.07 16:53:45 -05'00'

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI)

cc: HFS-255 Ott
File: FCN No. 2191

[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) 2191, submitted by Daikin America, Inc., for the use of 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and 4-hydroxybutyl acrylate, acetates (salts), added at the size press, to impart grease and oil resistance to paper and paperboard, except 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 October 1, 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 in paper and paperboard that contacts all food types under Conditions of Use A through H, except for use in contact with infant formula and human milk. As such, these uses were not included as part of the intended use of the substance in the FCN. Any waste materials generated in the process of producing the pads is expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

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*.[2] 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.[3]

Finally, the FCS is a high molecular weight polymer that does not readily volatize and is expected to remain with the finished food-contact article. 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.

[2] We note that in Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA. Please see the following links:

- https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf
- https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

We note that this report does not impact the conclusions presented in the EA, so no revision was required. However, the notifier was advised to utilize these reports in their future submissions.

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

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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2191 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 Date: 2022.01.07 16:54:15 -05'00' Date: see electronic signature

Brittany Ott, Ph.D.
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Office of Food Additive Safety
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Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.01.07 17:21:04 -05'00' Date: see electronic signature

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