U.S. FOOD & DRUG ADMINISTRATION

# Memorandum

**Date:** April 18, 2024

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

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2354

**Notifier:** Daikin America, Inc.

**To:** Lillian Mawby, 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: 2024.04.23 12:37:14 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2354, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2354 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, acetate (salts), added at the size press to impart grease and oil resistance to paper and paperboard.

The maximum application rate for the FCS is 0.6 g/m2 of the dry paper and paperboard. Finished food-contact paper and paperboard containing the FCS may contact all types of food under Conditions of Use A through H and J. The FCS is not 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.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated January 25, 2024 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: 2024.04.23 12:33:31 -04'00'

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Attachment: Finding of No Significant Impact (FONSI)

## FINDING OF NO SIGNIFICANT IMPACT

**Proposed Action:** Food Contact Substance Notification (FCN) 2354, 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, acetate (salts), added at the size press to impart grease and oil resistance to paper and paperboard, excluding 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 January 25, 2024. 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 expected to be entirely incorporated into and remain with the finished food-contact paper and paperboard and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in this process, e.g. plant scraps, are 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 density and then disposed of nationwide via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.[1]

Post-consumer disposal of food-contact articles manufactured with the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. EPA's 2020 data on Paper and Paperboard products states that of "67,390,000 tons of paper and paperboard present in municipal solid waste (MSW) generated in 2018, approximately 25.6% was land disposed, 6.2% was combusted, and 68.2% was recovered for recycling".[2] Calculations and data provided in a Confidential attachment, using the confidential FCS annual market volume, support that CO2-e emissions resulting from incineration of articles containing the FCS are below the 25,000 metric ton EPA reporting threshold (40 CFR 98). It is possible, since the FCS imparts grease- and oil-resistance, that more of the paper and paperboard will be combusted as a result of not being recycled. However, even if 100% of the product was combusted, the CO2-e emissions would still be well below the reporting threshold.

Due to the polymeric nature of the FCS, virtually no leaching of potential migrants from the finished food-contact article into aquatic or terrestrial environments indicates that there is no anticipated significant impact on environmental concentrations of the FCS, including during combustion of the food-contact articles. 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.

[1]Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020 ( https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

[2] Advancing Sustainable Materials Management: 2018 Tables and Figures, U.S. Environmental Protection Agency, December 2020, Table 5 (Paper and Paperboard Products in MSW, 2018), page 6, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

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 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2354 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: 2024.04.23 12:33:57 -04'00'

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