Memorandum

Date: June 23, 2025

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Review Team, Office of Food Chemical Safety, Dietary Supplements and Innovation, Office of Pre-Market Additive Safety

To: Stevie Walters, Ph.D., Regulatory Review Scientist, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Chemical Safety, Dietary Supplements and Innovation, Office of Pre-Market Additive Safety

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.06.24 15:09:01 -04'00'

Subject: Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2440

Notifier: Milliken Chemical

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2440, which is for the use of 5-[[[cis-4-(1,1-Dimethylethyl)cyclohexyl]carbonyl]amino]-N1,N3-bis[cis-4-(1-methylethyl)cyclohexyl]-1,3-benzenedicarboxamide (CAS Reg. No. 2649373-38-4) as a clarifying agent in polypropylene homopolymers and copolymers, including infant formula and human milk.

This 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 notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 31, 2025, 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 -S Digitally signed by Antonetta Thompson-wood -S Date: 2025.06.23 07:09:49 -04'00'

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 24040, submitted by Milliken Chemical for the use of 5-[[[cis-4-(1,1-Dimethylethyl)cyclohexyl]carbonyl]amino]-N1,N3-bis[cis-4-(1-methylethyl)cyclohexyl]-1,3-benzenedicarboxamide (CAS Reg. No. 2649373-38-4). The FCS is for use as a clarifying agent in polypropylene homopolymers and copolymers, including infant formula and human milk. The FCS is for use at levels not to exceed 0.08 weight percent of the finished polymer that may contact all food types, except for those containing more than 15% alcohol, under Conditions of Use A through H and J (microwave-only, excluding susceptor applications), as described in Tables 1 and 2. The FCS may be used in repeated-use articles (other than baby bottle nipples) intended for the feeding of infants (e.g., baby bottles).

The Office of Pre-Market 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 March 31, 2025. 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 finished articles and will remain with the finished food-contact articles throughout the use and disposal. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the finished article manufacturer's overall non-hazardous solid waste in accordance with established.

Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the 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: 2018 Fact Sheet.[1]

Post-consumer disposal of food-contact articles containing the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. 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. Further, because of the regulations at 40 CFR Part 60, and others, no significant impacts are expected from incineration of the FCS at MWCs. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

Further, according to data cited in the EA, when combusted, there is nothing to suggest that the FCS would threaten a violation of 40 CFR 60 or other regulations governing MWCs.

Manufacture of the FCS will consume comparable amounts of energy and resources as polypropylene containing other clarifying agents. Food-contact articles produced from resins containing the FCS are expected to be disposed of according to the same patterns when it is used in place of current materials. Therefore, no net increase in the use of energy and resources from the use and disposal of food-contact

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

articles manufactured with the FCS is expected. Considering the low level (0.08%) at which the FCS is added to the polymer, there is no impact on current or future recycling programs.

No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with 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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2440 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Antonetta Thompson-wood -S Digitally signed by Antonetta Thompson-wood -S Date: 2025.06.23 07:10:16 -04'00'

Antonetta Thompson-Wood, M.S.
Physical Scientist, Environmental Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
Food and Drug Administration

Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.06.24 15:09:34 -04'00'

Mariellen Pfeil
Supervisory Biologist, Environmental Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
Food and Drug Administration