
Memorandum

Date: April 21, 2021

To: Vivian Gilliam, M.S. Division of Food Contact Substances (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

From: Abigail E. Miller, Ph.D., Chemist, Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2127: Poly(tetramethylene terephthalate)(CAS Reg. No. 24968-12-5 and 26062-94-2) as manufactured from terephthalic acid and 1,4-butanediol.

Notifier: Mitsubishi Engineering-Plastics Corporation.

Attached is the FONSI for FCN 2127, which is for the use of poly(tetramethylene terephthalate)(CAS Reg. No. 24968-12-5 and 26062-94-2) as manufactured from terephthalic acid and 1,4-butanediol as base polymer in single-use and repeat-use articles, except for use in contact 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 March 25, 2021, 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.

Abigail E. Miller, Ph.D.

Attachments:

Finding of No Significant Impact (FONSI),
Environmental Assessment (EA) Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2089, submitted by Mitsubishi Engineering-Plastics Corporation for the use of poly(tetramethylene terephthalate)(CAS Reg. No. 24968-12-5 and 26062-94-2) as manufactured from terephthalic acid and 1,4-butanediol for use as a base polymer used in the manufacture of single- and repeat-use food contact articles, except for use in contact with infant formula and human milk. The FCS may be used in contact with all food types, except for infant formula and human milk under Conditions of Use A through H 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 4/2/2021).

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 March 25, 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 to be used as a base polymer of food contact articles. Food-contact articles containing the FCS will be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Fact Sheet December 2020¹. Items containing the FCS are not expected to be recycled, therefore they will not impact recycling. Post-consumer disposal of food-contact articles containing the FCS will be to landfills and municipal waste combustors (MWC) 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. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are 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 EA also considered the impact of greenhouse gas (GHG) emissions. However, based on estimated market volume information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2), of 25,000 metric tons CO₂-e. Therefore, significant impacts to the environment are not 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/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf
www.fda.gov

As evaluated in the EA, the proposed use of the FCS as described in FCN 2127 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 04-21-2021

Abigail E. Miller

Chemist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 04-23-2021

Mariellen Pfeil

Lead Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

U.S. Food and Drug Administration

Revision Sheet for the March 25, 2021 EA for FCN 2127

Revision Sheet Dated: April 2, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated March 25, 2021 for food contact notification (FCN) concluded that the action 2127 will not constitute a significant impact. This revision is issued to make a minor changes and updates 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:

1. Page 2, footnote 1 of the EA references the “United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Fact Sheet, November 2020.”

The Fact Sheet was updated to “December 2020”, but the distribution of disposal did not change between the November 2020 and the December 2020 versions of the Fact Sheets. Therefore, the most up to date reference would be: “United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Fact Sheet, December 2020.”

2. Page 1, Section 4.b “..will be sold to manufacturers engaged in production of the food contact articles or films for single use.” is replaced with “..will be sold to manufacturers engaged in production of the food contact articles or films.”

Removal of “For single use” aligns with the reviewed intended use. It can be removed because, in this case, whether the FCS is used in single or repeat use articles will not impact the disposal patterns.