
Memorandum

Date: October 5, 2020

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

To: Vanee Komolprasert, Ph.D., P.E. Division of Food Contact Substances (HFS-275)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2089: Terephthalic acid polymer with 1,4:3,6-dianhydro-D-glucitol, 1,4-cyclohexanedimethanol and 1,2-ethanediol (CAS Reg. No. 1038843-64-9) and optionally prepared with trimellitic anhydride (CAS Reg. No. 552-30-7) as a branching agent.

Notifier: SK Chemicals Co., Ltd.

Attached is the FONSI for FCN 2089, which is for the use of terephthalic acid polymer with 1,4:3,6-dianhydro-D-glucitol, 1,4-cyclohexanedimethanol and 1,2-ethanediol (CAS Reg. No. 1038843-64-9) and optionally prepared with trimellitic anhydride (CAS Reg. No. 552-30-7) as a branching agent as a component of articles in contact with food, including 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 September 25, 2020, 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.

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2089, submitted by SK Chemicals Co., Ltd. for the use of terephthalic acid polymer with 1,4:3,6-dianhydro-D-glucitol, 1,4-cyclohexanedimethanol and 1,2-ethanediol (CAS Reg. No. 1038843-64-9) and optionally prepared with trimellitic anhydride (CAS Reg. No. 552-30-7) as a branching agent as a component of articles in contact with food, including infant formula and human milk. The FCS may be in contact with all food types 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 10/5/20). The FCS may be used in repeat-use articles in contact with infant formula and human milk.

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 September 25, 2020. 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 component of articles in contact with food, including infant formula and human milk. The FCS has properties such as thermal stability and versatility. The inclusion of trimellitic anhydride (TMA) increases the heat distortion temperature (HDT) of a polymer resin. Raising the HDT of a polymer increases the temperature at which the material begins to soften under a fixed load.¹ Food-contact articles containing the FCS will be utilized in patterns corresponding to population and disposal, recycling and combustion rates provided in The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2016 and 2017 Tables and Figures.² Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively and recycled. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. 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. 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.

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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2089 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 10-05-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration

Approved by _____ Date: digitally signed 10-05-2020
Mariellen Pfeil, Lead Biologist, Environmental Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration

¹ Polymer Properties Database (2105). *Heat Distortion Temperature*. Available at <http://polymerdatabase.com/polymer%20physics/HeatDistortion.html>

² https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf
www.fda.gov

U.S. Food and Drug Administration Revision Sheet for the Sep. 25, 2020 EA for FCN 2089

Revision Sheet Date: October 5, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated September 25, 2020 for food contact notification (FCN) concluded that the action 2089 will not constitute a significant impact. This revision is issued to make a minor change and update 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:

- Page 1 of the EA states:

“Thus, the action requested in this FCN is to permit the subject Notifier’s ECOZEN polymer (CASRN: 1038843-64-9) for use in articles or as components of articles that contact food and beverages, including in repeat-use articles in contact with infant formula and human milk.”

To reflect the final language for this notification, this statement should state:

“Thus, the action requested in this FCN is to permit the subject Notifier’s ECOZEN polymer (CASRN: 1038843-64-9) for use as a component of articles in contact with food, including infant formula and human milk.”

- Page 2 of the EA states:

“The FCS has a molecular weight much greater than 10,000 Daltons, and it is considered a high molecular weight polymer.”

To support that substances greater than 10,000 Daltons are considered a high molecular weight polymer, this statement should have a footnote referencing the following web site: U.S. Environmental Protection Agency. High Molecular Weight Polymers in the New Chemicals Program. Available at [<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>]

- Page 4 of the EA states:

“Moreover, ECOZEN polymers are high molecular weight polymers (as detailed in Section 5) that contain no inorganic components or elements (i.e., metals), as detailed in the structural formula which could leach out of the polymer under landfill conditions.”

To reflect that the structural formula is provided in the confidential attachment (CA) to the EA, this statement should state:

“Moreover, ECOZEN polymers are high molecular weight polymers (as detailed in Section 5) that contain no inorganic components or elements (i.e., metals), as detailed in the structural formula (provided in the confidential attachment to the EA) which could leach out of the polymer under landfill conditions.”