

Memorandum

Date: May 3, 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) 2220: Copolymer of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), methacrylic acid (CAS Reg. No. 79-41-4), n-butyl acrylate (CAS Reg. No. 141-32-2), methyl methacrylate (CAS Reg. No. 80-62-6), and, optionally, acrylic acid (CAS Reg. No. 79-10-7) and/or α-methylstyrene dimer (CAS Reg. No. 6362-80-7).

Notifier: Harima Chemicals, Inc., Plasmine Technology, Inc.

To: Vanee Komolprasert, 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

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2220, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2220 is for the use of a copolymer of styrene, α-methylstyrene, methacrylic acid, n-butyl acrylate, methyl methacrylate, and, optionally, acrylic acid and/or α-methylstyrene dimer as an emulsifier for wet end chemicals in the production of food-contact paper and paperboard, including infant formula and human milk. The FCS will be used at a level not to exceed 0.163% by weight in the finished paper and paperboard that contact all food types (including infant formula and human milk) under Conditions of Use A through H, as described in Tables 1 and 2¹.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 31, 2022 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.

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Brittany Ott -S
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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

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) 2220, submitted by Harima Chemicals, Inc., Plasmine Technology, Inc. for the use of a copolymer of styrene, α-methylstyrene, methacrylic acid, n-butyl acrylate, methyl methacrylate, and, optionally, acrylic acid and/or α-methylstyrene dimer as an emulsifier for wet end chemicals in the production of food-contact paper and paperboard, including 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 March 31, 2022. 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 as an emulsifier for wet end chemicals in the production of food-contact paper and paperboard. The FCS will be used at a level not to exceed 0.163% by weight in the finished paper and paperboard that contact all food types (including infant formula and human milk) under Conditions of Use A through H, as described in Tables 1 and 2². The FCS will be sold to manufacturers engaged in the production of the finished food contact articles. Ultimate consumer disposal of the resultant paper and paperboard products will be by conventional rubbish disposal (sanitary landfill, incineration, or recycling).

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*. Post-consumer disposal of food-contact articles containing the FCS will be by recycling, landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The FCS contains carbon, hydrogen, and oxygen elements commonly found in MSW, and the expected carbon dioxide equivalent emissions, based upon a conservative 100 % FCS paper retention assumption, are below the 25,000 metric ton EPA reporting threshold.

The FCS is expected to mainly be removed from the finished food article; however, it is not reasonable to anticipate that the FCS would either remain in its entirety with the paper production process water, nor would it be entirely substantive to the finished paper. Rather, portions of the FCS will remain with the process water and the remainder will be substantive to the paper. As such, for the sake of conservatism, the notifier assumed that all the FCS will enter the wastewater and calculated the environmental impacts respectively. Although no specific data exists on the polyanionic FCS, the EPA recognizes the appropriateness of evaluating environmental fate using the nearest analog method for this class of polymer³, which in this case would be poly(carboxylic acids). In general poly(carboxylic acids) and poly(carboxylates) do not adversely impact wastewater treatment operations, and have an overall removal rate in conventional wastewater treatment that ranges from 82% to 97%. With a conservative assumption of an only 80% removal rate, the estimated environmental concentration (EEC) within the white water is well below any environmentally significant value. Any sludge containing the FCS will either be landfilled or land applied. The calculated concentrations of the FCS within the sludge show that, if land applied, the EEC is well below the No-Observed Effect Concentrations for plants and other land-dwelling organisms. Finally, due to the polymeric nature of the FCS, virtually no leaching is expected under normal conditions when landfilled.

² <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

³ United States Environmental Protection Agency Memorandum: Environmental Concerns of Polymers, February 1, 1991

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 2220 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

Brittany Ott -S

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Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by

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