
Memorandum

Date: April 21, 2021

To: Sean Fischer, Ph.D. Division of Food Contact Substances (HFS-275)

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

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2130: Acetic acid ethenyl ester, polymer with N-ethenylformamide, hydrolyzed, amine-containing (CAS Reg. No. 163879-68-3)

Notifier: Sekisui Specialty Chemicals America, LLC

Attached is the FONSI for FCN 2130, which is for the use of acetic acid ethenyl ester, polymer with N-ethenylformamide, hydrolyzed, amine-containing (CAS Reg. No. 163879-68-3) for use as a creping agent in the manufacture of paper. 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 February 11, 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.

Antonetta Thompson-Wood

Attachments:

Finding of No Significant Impact (FONSI)

Environmental Assessment (EA) Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2130, submitted by Sekisui Specialty Chemicals America, LLC for the use of acetic acid ethenyl ester, polymer with N-ethenylformamide, hydrolyzed, amine-containing (CAS Reg. No. 163879-69-3) as a creping agent in the manufacture of paper. The FCS may be used at levels not to exceed 25.8 µg/in² of paper in contact with all food types under Conditions of Use A through H as described in FDA Tables 1 and 2 (<https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>, accessed 4/21/21).

The FCS is not intended 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.

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 February 11, 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 creping agent in the manufacture of paper. Food-contact articles containing the FCS will be utilized in patterns corresponding to the national 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 Sheet¹. 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. 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.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on 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 25,000 metric tons CO₂-e, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

No net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected. No mitigation measures are needed since no 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.

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

As evaluated in the EA, the proposed use of the FCS as described in FCN 2130 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 04-25-2021

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 04-26-2021

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 February 11, 2021 EA for FCN 2130

Revision Sheet Dated: April 21, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated February 11, 2021 for food contact notification (FCN) 2130 concluded that the action 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 and Confidential Attachment to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

Page 3, paragraph 5, of the EA incorrectly states the FCS elemental composition. Thus, the sentence,

"Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, and hydrogen, elements that are commonly found in MSW."

Is revised to state:

"Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in MSW."