

Memorandum

Date: September 1, 2023

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2313

Notifier: Sun Chemical Corporation

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)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2023.09.01 11:07:01 -04'00'

Attached is the FONSI for FCN 2313, which is for the use of 2,5-Dihydro-3,6-bis(4-methylphenyl)pyrrolo[3,4-c]pyrrole-1,4-dione (CAS Reg. No. 84632-66-6) as a colorant in all food contact polymers. 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 FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated August 19, 2023, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S
Date: 2023.09.01 09:50:08 -04'00'

Denis Wafula, Ph.D.

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2313, submitted by Sun Chemical Corporation for the use of 2,5-Dihydro-3,6-bis(4-methylphenyl)pyrrolo[3,4-c]pyrrole-1,4-dione (CAS Reg. No. 84632-66-6) as a colorant in all food contact polymers. The FCS may be used at levels up to 0.2% by weight of polymers in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2,¹ respectively. The FCS is not 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 August 19, 2023. 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.

Items manufactured with the FCS are expected to be land disposed, combusted, or recycled proportionately with the current national municipal solid waste (MSW) disposal patterns. Discarded items will go to landfills or MSW combustion facilities complying with 40 CFR Parts 258 and 60, respectively. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. Because the recycling industry is already configured to process colored polymers, recycling of food-contact articles containing the FCS through will not interfere with recycling.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>
www.fda.gov

As evaluated in the EA, the use of the FCS as described in FCN 2313 will not significantly affect the human environment. Therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S
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Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
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