# Memorandum

**Date:** February 3, 2020

**To:** Jessica Urbelis, Ph.D., Division of Food Contact Substances (HFS-275)
**Through:** Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Office of Food Additive Safety, HFS-255

**From**: Staff Fellow, Environmental Team, Division of Science and Technology (HFS-255)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2026: Blocked isophorone diisocyanate (IPDI) polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer (CAS Registry Number 103170-26-9).

**Notifier:** The Sherwin-Williams Company

Attached is the FONSI for FCN 2026 which is for the use of blocked isophorone diisocyanate (IPDI) polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer (CAS Registry Number 103170-26-9). 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, and the notifier's environmental assessment (EA), dated December 13, 2019, 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

Attachment: FONSI

# FINDING OF NO SIGNIFICANT IMPACT

**Food Contact Substance Notification (FCN) 2026**, submitted by The Sherwin-Williams Company for the use of blocked isophorone diisocyanate (IPDI) polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer (CAS Registry Number 103170-26-9) as a monomeric component in polyester urethane coatings for use on metal substrates, at a maximum concentration of 9.4% (weight solids). Coatings containing the FCS may contact 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 1/28/2020). 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 December 13, 2019. 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 a monomeric component in polyester urethane coatings for use on metal substrates, at a maximum concentration of 9.4% (weight solids). Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills complying with 40 CFR Part 258; municipal waste combustors (MWC) complying with 40 CFR Part 60 and through recycling. 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. According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), including nitrous oxide (N2O), represented as CO2-equivalent (CO2-e) in metric tons (mT), are 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 MWC facilities. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant impacts are expected from use of the FCS. 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 2026 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 02-03-2020
Denis Wafula Ph.D.
Staff Fellow, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 02-03-2020
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