U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: April 4, 2025

From: Biologist, Office of Pre-Market Additive Safety, Environmental Review Team

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2428

Notifier: Solenis LLC

To: Nicole Morris-Anastasi, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist, Office of Pre-Market Additive Safety, Environmental Review Team

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
Date: 2025.04.04 14:35:54 -04'00'

Attached is the FONSI for FCN 2428, which is for the use of 5,5-Dimethylhydantoin (DMH) (CAS Reg. No. 77-71-4) intended for use as a stabilizer for hypohalite slimicides used in the manufacture of food-contact paper and paperboard. 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 notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated January 9, 2025, 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: 2025.04.04 14:08:44-04'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2428, submitted by Solenis LLC for the use of 5,5-Dimethylhydantoin (DMH) (CAS Reg. No. 77-71-4) intended for use as a stabilizer for hypohalite slimicides used in the manufacture of food-contact paper and paperboard. The FCS will be used at a level not to exceed 0.5 g DMH per kg of dry fiber. The paper and paperboard containing the FCS may be used in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2.[1] The FCS is not for use in contact with infant formula or 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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment, dated January 9, 2025. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Food-contact articles containing the FCS are expected to be disposed by landfilling, incineration at municipal solid waste (MSW) combustors, or through recycling. All pathways of disposal will occur at rates proportional to the national MSW disposal patterns for similar products. It is anticipated that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of such articles. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore 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. Recycling of food-contact articles containing the FCS is not expected to affect existing recycling programs.

The FCS will be used during in the wet-end phase of the papermaking process. To calculate the environmental introduction concentration (EIC) of the FCS, the notifier conservatively assumes that at the wet-end phase of papermaking, the concentration of solids will be 1% by weight. Because the use level of the FCS is 0.5 g (500 ppm) per kg of fiber, the estimated EIC is 5 ppm. The notifier further assumes a 10-fold dilution factor for discharge to surface waters resulting in estimated environmental concentration (EEC) of 5 ppm and 0.5 ppm in sludge and treated waters, respectively.

If applied as a soil amendment, the sludge will be mixed with soil and therefore the concentration of any adsorbed FCS will be further diluted. Even without the reasonably expected dilution, the available ecotoxicity endpoints for terrestrial subjects such as earthworms and plants suggest no realistic concern at the < 5.0 mg/kg concentration considered from the proposed use. The aquatic EEC of 0.5 ppm (assuming no further biodegradation) is orders of magnitude below the lowest acute and long-term aquatic ecotoxicological endpoints for DMH. With the lowest values being an EC_{50} > 125 ppm for eastern oysters and a LOEC of 29 ppm for Fathead minnows. Therefore, discharge to surface waters is not expected to have any significant environmental impacts.

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 be used in place of similar substances that are already in use. Manufacture of the FCS and its use in

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

food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of chemically related stabilizers 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.

Consequently, we find that use of the FCS as a stabilizer for hypohalite slimicides used in the manufacture of food-contact paper and paperboard will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2025.04.04 14:09:22 -04'00'

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Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.04.04 14:36:42 -04'00'

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