

## Memorandum

**Date:** May 16, 2024

**From:** Leah D. Proffitt, Biologist, Environmental Team, Division of Science and Technology (HFS-255)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2360

**Notifier:** Wanhua Chemical Group Co., Ltd.

**To:** Joshua Moskowitz, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)

**Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S  
Date: 2024.05.16 09:02:32 -04'00'

**Through:** Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Attached is the FONSI for FCN 2360 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2360 is for the use of 1H-azepine-1-carboxamide,N,N',N''-[(2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)- triyl)tris[methylene(3,5,5-trimethyl-3,1-cyclohexanediy)]]tris[hexahydro-2-oxo- (CAS Reg. No. 68975-83-7), as a reactant with one or more polybasic acids or polyhydric alcohols in the formation of coatings on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications, complying with 21 CFR 175.300(b)(3)(vii), except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated April 8, 2024, 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.

**Leah D. Proffitt -S** Digitally signed by Leah D. Proffitt -S  
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Leah D. Proffitt

**Attachment:** Finding of No Significant Impact

## FINDING OF NO SIGNIFICANT IMPACT

**Food Contact Substance (FCS) Notification (FCN) 2360:** submitted by Wanhua Chemical Co., Ltd., for the safe use of 1H-azepine-1-carboxamide,N,N',N''-[(2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triy)]tris[methylene(3,5,5-trimethyl-3,1-cyclohexanediy)]]tris[hexahydro-2-oxo- (CAS Reg. No. 68975-83-7), as a reactant with one or more polybasic acids or polyhydric alcohols in the formation of coatings on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications, complying with 21 CFR 175.300(b)(3)(vii), except for use in contact with infant formula and human milk.

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 April 8, 2024. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

The FCS will be used in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2.

Items manufactured with the FCS are expected to be land disposed or combusted proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2018 Tables and Figures." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. As the FCS is similar to other caprolactam-blocked IPDI trimer coatings used as metal can coatings, we do not expect the FCS to interfere with current recycling patterns or programs. 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.

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.

Consequently, we find that use of the FCS in the formation of coatings on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by **Leah D. Proffitt -S** Digitally signed by Leah D. Proffitt - S  
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Approved by **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S  
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