



Memorandum

Date: September 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) 2453

Notifier: Coatex SAS

To: Lillian Mawby, Ph.D., Regulatory Review Scientist, 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 - Digitally signed by MARIELLEN PFEIL -S
Date: 2025.09.04 16:39:07 -04'00'

Attached is the FONSI for FCN 2453, which is for the use of 2-Propenoic acid, polymer with sodium phosphinate (1:1), neutralized as sodium salt (CAS Reg. No. 129898-01-7), magnesium sodium salt (CAS Reg. No. 935545-65-6), calcium sodium salt, or calcium magnesium sodium salt as an aid for dispersing and grinding mineral fillers in the wet-end process during the manufacture of food contact paper and paperboard used as packaging, including for use in contact with powdered (dry) infant formula. 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 April 25, 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: 2025.09.04 09:22:05 -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) 2453, submitted by Coatex SAS for the use of 2-Propenoic acid, polymer with sodium phosphinate (1:1), neutralized as sodium salt (CAS Reg. No. 129898-01-7), magnesium sodium salt (CAS Reg. No. 935545-65-6), calcium sodium salt, or calcium magnesium sodium salt as an aid for dispersing and grinding mineral fillers in the wet-end process during the manufacture of food contact paper and paperboard used as packaging, including for use in contact with powdered (dry) infant formula. The FCS will be used at levels not to exceed 0.5 percent by weight in the filler. For use in contact with all foods types except food types VIA and VIC under Conditions of Use C through G.¹ The FCS may be used in contact with powdered (dry) infant formula.

The Office of Pre-Market 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 25, 2025. 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 functions as a grinding and dispersing aid for mineral fillers during the production of food-contact paper and paperboard materials. Neither the manufacturing of the FCS nor the production of food-contact articles containing the FCS is anticipated to generate significant environmental impacts. During the papermaking process, the FCS will be released into the white water system and may eventually enter the environment through wastewater discharge and land application of treatment sludge. The environmental assessment (EA) indicates that the maximum FCS concentration entering the white water is 2 ppm. This concentration represents the worst-case environmental release scenario for both aquatic and terrestrial environments, since dilution effects, partitioning processes, and biodegradation during wastewater treatment are expected to reduce the actual environmental concentrations below this level.

After manufacture and subsequent use, food-contact articles containing the FCS will be disposed of via recycling, landfilling, or combustion. We do not expect any negative impact on recycling because the FCS will not affect the fitness of materials for recycling. With regard to disposal by landfilling and combustion, based on the amount of the FCS added during manufacture of food-contact articles, the FCS will comprise a very small portion of the total municipal solid waste (MSW) landfilled and combusted. Because of the Environmental Protection Agency's (EPA's) regulations governing landfills (40 CFR Part 258), no significant amounts of the FCS are expected to be introduced into the environment when disposed of at properly operating, permitted landfills. The combustion of food-contact articles containing the FCS in properly operating, permitted MSW combustion facilities 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. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

The worst-case environmental introduction concentration (2 ppm) of the FCS is sufficiently below both terrestrial and aquatic ecotoxicity endpoints such that any release of the FCS into the environment is not expected to have any adverse effect on organisms present in these environments. The EA (in a confidential attachment) provides a 72-hour algal growth inhibition study using *Pseudokirchneriella subcapitata* that showed no observed effects at concentrations of >100 mg/L. The EA also indicates that 96-hour acute toxicity tests

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

showed that the LC₅₀ for rainbow trout (*Oncorhynchus mykiss*) and zebrafish (*Danio rerio*) was >1,000 mg/L, while the value for brown shrimp (*Crangon crangon*) was >10,000 mg/L. The EA also identifies terrestrial endpoints in plants (225 mg/kg NOEC in corn, wheat, and soybean) which are above the estimated concentration of the FCS in sludge (<1.96 mg/kg) which can be landfilled or land-applied as fertilizer.

We do not expect a net increase in the use of energy and resources from the use of the FCS because it is intended to compete with and/or replace existing products that are authorized for the same use. Additionally, we do not identify any adverse environmental effects that would necessitate alternative actions to those proposed in the FCN. The alternative of not approving the action proposed herein would result in the continued use of the materials that the FCS would otherwise replace; such action would have no environmental impact. Furthermore, because the use and disposal of the FCS are not expected to result in significant adverse environmental impacts, no mitigation measures are identified. As evaluated in FCN 2453, the use of the FCS as an aid in the dispersing and grinding of mineral fillers in the wet-end during the manufacture of food-contact paper and paperboard will not significantly affect the quality of the human environment; therefore, an EIS will not be required.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S
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Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
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