

Memorandum

Date: April 10, 2019

To: Kenneth McAdams, Division of Food Contact Notifications (HFS-275)

Through: Leah Proffitt, Acting Environmental Supervisor, Office of Food Additive Safety, HFS-255

From: Staff Fellow, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1956 for 2-propenoic acid, polymer with sodium phosphinate (1:1), neutralized with sodium, calcium, and/or magnesium (including CAS Reg. No. 129898-01-7 [Na salt], CAS Reg. No. 935545-65-6 [Mg Na salt]).

Notifier: Coatex SAS

Attached is the Finding of No Significant Impact (FONSI) for FCN 1956 for 2-propenoic acid, polymer with sodium phosphinate (1:1), neutralized with sodium, calcium, and/or magnesium (including CAS Reg. No. 129898-01-7 [Na salt], CAS Reg. No. 935545-65-6 [Mg Na salt]).

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated March 8, 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: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1956), submitted by Coatex SAS for the use of 2-propenoic acid, polymer with sodium phosphinate (1:1), neutralized with sodium, calcium, and/or magnesium (including CAS Reg. No. 129898-01-7 [Na salt], CAS Reg. No. 935545-65-6 [Mg Na salt]) as described below.

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, dated March 8, 2019. 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.

The food-contact substance (FCS) is intended to be used at levels not to exceed 0.5 percent by weight as an aid for dispersing and grinding mineral fillers in the wet-end during the manufacture of food-contact paper and paperboard, except for use in contact with infant formula and human milk. The FCS is intended for use in contact with food types I, II, III, IVA, IVB, V, VIB, VIIA, VIIIB, VIII, and IX under conditions of use C through G.

The FCS aids in the grinding and dispersing of mineral fillers during the manufacture of food-contact paper or paperboard materials. Manufacture of the FCS or food-contact articles containing the FCS is not expected to result in significant environmental impact. The FCS will be lost with the white water associated with paper making, and ultimately may reach the environment via water and land applied sludge. According to the EA, the maximum concentration of the FCS that will enter the white water is 2 ppm. In our analysis, the 2 ppm is used as a worst-case environmental introduction concentration in water and in sludge (since dilution, further partitioning in wastewater treatment facilities, and biodegradation are likely to decrease this concentration).

After manufacture and subsequent use, food-contact articles containing the FCS will be disposed via recycling, landfilling, or combustion. We do not expect any negative impact to 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 make up 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 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. The EA also considered the impact of greenhouse gas (GHG) emissions and estimated the total annual emissions of GHGs, represented as carbon dioxide equivalents (CO₂-e) in metric tons (mT). The GHG estimate is 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.

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 the 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 showed that the LC₅₀ for rainbow trout (*Oncorhynchus mykiss*) and Zebra fish (*Danio rerio*) was >1000mg/L.

While the value for brown shrimp (*Crangon crangon*) was >10000 mg/L. The EA also identifies terrestrial endpoints in plants (225 mg/kg NOEC in corn, wheat, and soybean).

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 which 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 1956, 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 prepared.

Prepared by _____ Date: see electronic signature
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Food and Drug Administration

Approved by _____ Date: see electronic signature
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