FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 5, 2018

To: Elizabeth Petro, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, 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 1922: 2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl, chloride (1:1), polymer with ethanedial and 2-propenamide, (CAS Reg. No. 32555-39-8)

Notifier: SNF SAS

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1922, which is for the use of 2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl, chloride (1:1), polymer with ethanedial and 2-propenamide as a dry- and wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard in contact with all food types, except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment, dated September 26, 2018, may be made available to the public. We will post digital transcriptions of the FONSI, and the environmental assessment 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

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1922, submitted by SNF SAS for the use 2-propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), polymer with ethanedial and 2- propenamide (CAS Reg. No. 32555-39-8), as a dry- and wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard in contact with all food types, except for use in infant formula and breast milk. The level of the FCS is not to exceed 0.5 percent by weight of the dry fibers in the paper and paperboard. The FCS will be used in contact with all food types under condition of use A through H.

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 September 26, 2018. 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 dry- and wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard. Most of the FCS will be incorporated into finished paper and paperboard and will remain in the food contact articles through use and disposal. Information provided in a confidential attachment to the EA shows that an insignificant amount of the FCS (if any) will end up in the whitewater effluent from the paper manufacturing process. The potential for environmental impact is predominantly from the release of residual monomers (diallyldimethylammonium chloride [DADMAC], acrylamide, and glyoxal) into white water during paper processing.

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 is already authorized for similar uses and therefore, food contact articles containing the FCS are already in the recycling chain. With regards to disposal by landfilling and combustion, information based on confidential market volume and the amount of the FCS added during manufacture of food contact articles indicates that 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 via landfill. The combustion of food contact articles containing the FCS is expected to result in the production of water, carbon dioxide, halogenated compounds and oxides of nitrogen. Based on its composition and on the fact that the FCS will form a miniscule portion of the total MSW combusted there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities. The EA in a (confidential attachment) 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.

As stated above, the potential for environmental impact is predominantly from the release of residual monomers into the whitewater effluent during paper manufacture. The environmental introduction concentrations (EICs) and expected environmental concentrations (EECs) of the monomers are provided in the EA and are sufficiently below 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 the aquatic environment.

Monomer	EEC (ppm)	Most Sensitive LC50 (ppm)
Acrylamide	0.03	33.85, 72h- EC50 *Selenastrum capricornutum*
Glyoxal	0.7	215, 96h- LC50 *Pimephales promelas* [1]
DADMAC	6.7	56, 72h- LC50 *Lepomis macrochirus*

[1] ***EA CORRECTION*** - On page 12 of the EA (Table labelled 'Most Sensitive LC/EC 50), the endpoint for glyoxal is stated as *Daphnia magna* at 48 h. This most sensitive endpoint (215 ppm, based on the EA and reference provided by the notifier) is LC50 for *Pimephales promelas* at 96 h

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 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 is not expected to result in significant adverse environmental impacts, no mitigation measures are identified. As evaluated in FCN 1922, the use of the FCS as a dry- and wet-strength agent employed prior to the sheet-forming operation in 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: digitally signed 11-05-2018
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Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 11-05-2018
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