U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 9, 2022

To: Sean Fischer, Ph.D., Division of Food Contact Substances, HFS-275

Through: Mariellen Pfeil, Lead Biologist, Office of Food Additive Safety, HFS-255

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.03.09 12:32:30 -05'00'

From: Biologist, Environmental Team, Division of Science and Technology, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2194 for 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-, sodium salt (1:1), polymer with 2-propenamide, reaction products with glyoxal (CAS Reg. No. 2614959-08-7).

Notifier: SNF SA

Attached is the Finding of No Significant Impact (FONSI) for FCN 2194 for use of the above-described FCS a dry- and wet-strength, drainage and dewatering agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated December 7, 2021, 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 Date: 2022.03.09 01:13:47 -05'00'

Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FCN No. 2194

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2194), submitted by SNF SA., to provide for the safe use of acrylamide polymer with 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-, sodium salt (1:1), polymer with 2-propenamide, reaction products with glyoxal (CAS Reg. No. 2614959-08-7), as a dry-and wet-strength, drainage and dewatering agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard, in contact with all food types, under Conditions of Use A through H, except for use in contact with infant formula and human milk. The FCS will be used at levels not to exceed 0.5 percent by weight of the dry fibers in the finished paper and paperboard.

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 December 7, 2021. 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 increase both the dry- and wet strength of paper and paperboard and will be used as an additive at the wet end of the paper and paperboard manufacturing processes in facilities throughout the United States. Paper processors are among those industries required by EPA to meet industry specific effluent pretreatment standards. Therefore, wastewater from the proposed use will be either discharged ultimately to a publicly-owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment.

The residual monomers acrylamide, glyoxal, and sodium 2-acrylamido-2-methylpropane-sulfonate (ATBS.Na), are not expected to be retained by the paper but to become components in the paper mill whitewater that will be sent to the on-site wastewater treatment facilities at paper mills. The effective environmental concentrations (EEC) of these monomers and most sensitive ecotoxocity endpoints for are as follows:

Acrylamide: 0.13 ppm << 100 mg/L 96-hr EC_{50} (*Lepomis macrochirus*); 98 mg/L 48-hr EC_{50} (*Daphnia magna)*

ATBS.Na: 0.26 ppm << 1000 mg/L 96-hr LC_{50} (*Lepomis macrochirus*); no effect on *D. magna* at 1000 mg/l

Glyoxal: 1.33 ppm << 215 mg/L 96-hr LC_{50} (*Pimephales promelas*); 404 mg/L 96-hr LC_{50} (*Daphnia magna)*

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. Since these items will not be recycled, they will not interfere with recycling patterns. 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.

Furthermore, 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.

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 dry-and wet-strength, drainage and dewatering agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S Date: 2022.03.09 01:14:25 -05'00' Date: see electronic signature

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Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.03.09 12:33:00 -05'00' Date: see electronic signature

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