FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: May 19, 2022

To: Jessica Urbelis, 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: 2022.05.19 12:00:38 -04'00'

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

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2222 for lignosulfonic acid, sodium salt (CAS Reg. No. 8061-51-6)

Notifier: CHEP USA

Attached is the Finding of No Significant Impact (FONSI) for FCN 22220 for use of the above-described FCS as a dispersant in a coating used on wooden pallets used for hydrocooling produce.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated April 8, 2222, 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: 2022.05.19 11:38:41 -04'00'

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2222), submitted by CHEP USA to provide for the safe use of lignosulfonic acid, sodium salt (CAS Reg. No. 8061-51-6), as a dispersant in a coating used on wooden pallets used for hydrocooling produce.

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, April 8, 2022. 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 FCS may be used at a level of 0.5% by weight in the coating. Pallets containing the FCS may be in contact with water used for hydrocooling produce.

Lignosulfonic acid, sodium salt incorporated in the fungicide PQ-8 formulation, is proposed for use as an indirect food additive through the pre-manufacture process of wood pallets used in post-harvest hydrocooling and related processing of fruits and vegetables to prevent ripening or decay throughout distribution. In the PQ-8 formulation, lignosulfonic acid, sodium salt functions as a dispersing agent. In hydrocooling water used to prevent pre-market ripening of fruits and vegetables, the FCS is not anticipated to exceed 3.1 ppm. The fungicide protects the wood from fungal damage and the wood pallets may be used in hydrocooling produce, which is an indirect food contact scenario. Fresh produce continues to respire after harvest and may wilt; precooling provides a non-chemical preservative method for fruit and vegetable processing, and keeps produce fresh through the distribution chain, maximizing the value of produce upon arrival at market.

The primary pathway by which the FCS is anticipated to be introduced to the environment is through the treatment and disposal of hydrocooling process wastewater generated over the approximately 10-year lifetime of a treated pallet. Hydrocooling water is recycled through multiple hydrocooling cycles before discharge via the sanitary sewer system to a publicly-owned treatment works (POTW). For calculation of the environmental introduction concentration (EIC) of lignosulfonic acid, sodium salt, the following worst-case assumptions were made:

- 100% of the FCS (3.1 ppm) migrates from pallets to wastewater
- 1000 gallons of water used during a 12-hour hydrocooling cycle
- POTW daily flow of 0.1 million gallons (100,000 gallons)

This yields an EIC of 0.031 ppm, or 31 ppb. Incorporating a 10-fold dilution factor to account for discharge to surface waters yields an effective environmental concentration (EEC) of 3.1 ppb.

The FCS is highly water soluble and degrades readily in the presence of microbes. Short-term toxicity values that have been identified include a 48-hour LC50 of 7,300 ppm in *Oncorhynchus mykiss* and a 96-hour LC50 of 615 ppm in *Pimephales promelas*. The aquatic effect levels for lignosulfonic acid, sodium salt are orders of magnitude higher than the EEC of 3.1ppb. In general, lignosulfonic acid, sodium salt is considered to be of low toxicological concern to aquatic organisms.

FCS-treated pallets may be disposed of in municipal solid waste systems throughout the United States (either in a landfill) or converted into mulch. Discarded pallets may also be disposed of at municipal solid waste (MSW) landfills or incinerated at a MSW combustion facility (complying with 40 CFR Parts 258 and 60, respectively). 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.

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 as a dispersant in a coating used on wooden pallets used for hydrocooling produce 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: 2022.05.19 11:39:30 -04'00' Date: see electronic signature

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