U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: April 12, 2017

To: Marla Swain, Ph.D., Division of Food Contact Notifications (HFS-275)

Through: Suzanne Hill, Environmental Supervisor, Office of Food Additive Safety, HFS-255

Suzanne Hill -S

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From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1768 for a solution of silver dihydrogen citrate (SDC) (CAS Reg. No. 127694-63-7) stabilized with sodium lauryl sulfate (SLS) and citric acid.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1768, request for use of a solution of silver dihydrogen citrate (SDC) stabilized with sodium lauryl sulfate (SLS) and citric acid at levels up to 160 ppm SDC in the spray applied to poultry carcasses, parts, and organs.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated March 3, 2017, 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

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Attachment: Finding of No Significant Impact

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FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1768), submitted by Pure Bioscience, to provide for safe use of use of a solution of silver dihydrogen citrate (SDC) (CAS Reg. No. 127694-63-7) stabilized with sodium lauryl sulfate (SLS), and citric acid at levels up to 160 ppm SDC in the spray applied to poultry carcasses, parts, and organs.

The Office of Food Additive Safety has determined that allowing this FCN to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement will not prepared. This finding is based on information submitted by the submitter in an environmental assessment, dated March 3, 2017. 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 inhibit the growth of undesirable or pathogenic microorganisms, and will be used in poultry processing facilities throughout the United States. As a worst-case disposal scenario, the EA evaluates disposal for facilities in possession of a National Pollutant Discharge Elimination System. For these facilities, disposal is via onsite wastewater treatment and ultimately surface waters.

Treatment at the onsite treatment plant is expected to result in near complete degradation of the citric acid, citrate and sodium laurel sulfate (SLS). Citric acid and SLS biodegrade at rates of 93% and 90%, respectively. Silver adsorbs to treatment sludge at 94%, with the remaining 6% being discharged to surface waters. Accounting for these degradation factors, adsorption rates, mixing with other waste water in the processing facility, and a 10-fold dilution when effluent is discharged to surface waters yields the following expected environmental concentrations (EEC):

- $\text{Silver}_{(aq)}$: 1.6 µg/L (ppb)
- $\text{Silver}_{(terr)}$251.9 µg/L
- SLS: 5.1 µg/L (ppb)
- Citric acid: 0.16 mg/L

The aquatic silver EEC of 1.6 µg/L is below the National Recommended Water Quality Criteria-Aquatic Life Criteria for Silver, which establishes a criterion maximum concentration (CMC) of 3.2 µg/L (acute). Applying EPA's Risk Presumption Approach, the Risk Quotient (RQ = EEC ÷ CMC) yields a Level of Concern (LOC) of 1.6 ÷ 3.2 = 0.5, which meets but does not exceed EPA's LOC of 0.5 for Acute High Risk for aquatic animals. We therefore find that an adequate margin of safety exists for discharges of silver in waste water from the requested use.

The terrestrial silver EEC of 251.9 µg/L is below the threshold for designation as Hazardous Waste if detected at 5 mg/L by Toxicity Characteristic Leaching Procedure (TCLP, EPA Method 1311). Therefore, sludge from the requested use may be disposed of as conventional municipal solid waste (MSW) if not sent for precious metals recovery. Silver is expected to be in the form of silver sulfide (Ag_2S); the terrestrial EEC (79.9 µg/L) is equivalent to 183.6 µg/L of silver sulfide as follows:

- (251.9 µg/L Ag) × ((247.8 g/mole Ag_2S) ÷ (107.868 g/mol Ag)) = 578.7 µg/L Ag_2S

The no observable effects concentration (NOEC) for silver sulfide for earthworms is 62 mg/kg soil. Adjusting for the density of sludge (1.5 g/cm^3), yields a NOEC of 93 mg/L. This ecotoxicity endpoint is 160 times higher than the terrestrial EEC of 578.7 µg/L. The predicted no effect concentration (PNEC) for citric acid on fish, *Daphnia*, and algae is 0.8 mg/L, which is higher than the above-cited EEC of 0.16 mg/L. Similarly, the EEC of 5.1 µg/L is well below the low observable effects concentration (LOEC) in *Scenedesmus quadricauda* for SLS is 0.02 mg/L, . Terrestrial EECs for citric acid and SLS were not calculated as those substances are not expected to adsorb to sludge.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, no mitigation measures are needed. The alternative of not allowing the exemption request would be use of other antimicrobials already on the market; such action would have no new significant environmental impact.

Consequently, we find that use of the FCS as described in FCN 1768 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 DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000397946, cn=Leah D. Proffitt -S Date: 2017.04.12 09:43:31 -04'00' Date: see electronic signature

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