

Memorandum

Date: December 11, 2019

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Substances (HFS-275)

Through: Leah D. Proffitt, Biologist, Environmental Team, Office of Food Additive Safety, HFS-255

From: Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2023:

A mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (CAS Reg. No. 7757-83-7).

Notifier: Brüggemann Chemical US, Inc.

Attached is the FONSI for FCN 2023, which is for the use of a mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (CAS Reg. No. 7757-83-7) as a reducing agent in emulsion polymerization redox catalyst systems. The produced polymers will be used as components of food contact articles. The FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated November 26, 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.

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2023, submitted by Brüggemann Chemical US, Inc. for the use of a mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (CAS Reg. No. 7757-83-7) for use as a reducing agent in emulsion polymerization redox catalyst systems. The produced polymers will be used as components of food contact articles. The FCS will be used at a maximum level of 1.0 percent based on total monomer weight of polymers produced, unless otherwise specified below. The polymers produced using the FCS may contact all food types, including infant formula and human milk (described as breast milk in the EA), under Conditions of Use A through H as described in Table 2 (<https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>, accessed 12/11/19) subject to any limitations on the use of such polymers under the 21 CFR regulations that provide for their intended use. The FCS may be used only in the production of: 1) Polymers to be used as components of pressure-sensitive adhesives complying with 21 CFR 175.125 2) Acrylic latex polymers to be used as components of coatings complying with 21 CFR 175.300. Coatings that are formed from the acrylic latex polymers will have a maximum thickness of 9 microns. For such coatings intended for use in contact with infant formula or human milk, the FCS will be used at a maximum level of 0.5 percent based on total monomer weight of the acrylic latex polymers produced 3) Polymers to be used as components of coatings for polyolefin films complying with 21 CFR 175.320. The coatings for polyolefin films will be applied at a maximum rate of 0.8 g/m² (equivalent to the 0.5 lb/ream described in the EA), of film 4) Polymers to be used as components of coatings for polyester film wherein both the coating and the polyester film comply with regulations under 21 CFR that provide for their intended use. The coatings for polyester films will be applied at a maximum rate of 0.8 g/m² of film.

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 November 26, 2019. 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 reducing agent in emulsion polymerization redox catalyst systems. The produced polymers will be used as components of food contact articles. Food-contact articles containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. In some of the applications, articles containing the FCS may be collected for recycling (e.g. acrylic coatings for cans); however, in most applications' food-contact materials containing the FCS are not expected to be collected for recycling. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Due to EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO₂-equivalent (CO₂-e) in metric tons (mT), are well 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 MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2023 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 12-11-2019

Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 12-11-2019

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