U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 15, 2024

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

To: Adriana Alexander, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2371

Notifier: Brüggemann Chemical US, Inc.

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2024.07.15 11:28:17 -04'00'

Attached is the FONSI for FCN 2371, which is for the use of Magnesium and zinc complexes with 10-40% hydroxy(sulfinato)acetate (CAS Reg. No. 743407-32-1), 20-60% hydroxy(sulfonato)acetate (CAS Reg. No. 5980-14-3), and 5-30% glyoxylate (CAS Reg. No.298-12-4) as a reducing agent in emulsion polymerization redox catalyst systems. This 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 dated April 22, 2024, 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 -S Digitally signed by Denis Wafula -S Date: 2024.07.15 11:22:56 -04'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2371, submitted by Brüggemann Chemical US, Inc., for the use of Magnesium and zinc complexes with 10-40% hydroxy(sulfinato)acetate (CAS Reg. No. 743407-32-1), 20-60% hydroxy(sulfonato)acetate (CAS Reg. No. 5980-14-3), and 5-30% glyoxylate (CAS Reg. No.298-12-4) 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, under Conditions of Use A through H as described in Table 2[1] 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 in the production of polymer emulsions to be used as components of:

1. Food-contact paper and paperboard complying with 21 CFR 176.170 or 176.180.
2. Adhesives complying with 21 CFR 175.105.
3. Pressure-sensitive adhesives complying with 21 CFR 175.125.
4. Repeat use rubber articles complying with 21 CFR 177.2600.
5. 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.
6. 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/m^2 of film.
7. 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/m^2 of film.

The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

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 April 22, 2024. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

Food-contact articles containing the FCS are expected to be disposed either by landfilling or by incineration at municipal solid waste (MSW) combustors at rates proportional to the national MSW disposal patterns for similar products. Food-contact articles containing the FCS are not expected be significantly disposed by recycling. It is anticipated that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of such articles. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore 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. Based on market volume information provided in the confidential attachment to the EA, 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 substitute other similar or identical substances already in use. Manufacture of the FCS and its

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

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.

The use of the FCS, as described in FCN 2371, as a reducing agent in emulsion polymerization redox catalyst systems will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by

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Approved by

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