

Memorandum

Date: August 21, 2019

To: Vanee Komolprasert, P.E., PhD., Division of Food Contact Substances (HFS-275)

Through: Sarah C. Winfield, Acting Team Lead, Office of Food Additive Safety (HFS-255)

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

Subject: Finding of No Significant Impact for Food Contact Substance Notification (FCN) 1993 for 1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt (1:1), polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol (CAS Reg No 27937-63-9).

Notifier: Matsumura Sangyo Co., Ltd.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1993 for 1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt (1:1), polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol (CAS Reg No 27937-63-9).

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated July 2, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed action: Food Contact Substance (FCS) Notification (FCN) 1993 submitted by Matsumura Sangyo Co., Ltd. for 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt (1:1), polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol (CAS Reg. No. 27937-63-9) as a surface treatment agent for talc added to inhibit hydrolysis of food-contact polymers. The FCS is used at a level not to exceed 1% by weight of talc. The FCS-containing talc is used at a level not to exceed 5% by weight of polyethylene terephthalate (PET), polybutylene terephthalate (PBT), and polylactic acid (PLA) polymer. The finished polymer may contact all food types under Condition of Use A-H, as described in Tables 1 and 2.¹ 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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated July 2, 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 and is briefly summarized below.

The FCS is a surface treatment agent for talc added to inhibit hydrolysis of food-contact polymers. The FCS is used at a level not to exceed 1% by weight of talc. The FCS-containing talc is used at a level not to exceed 5% by weight of polyethylene terephthalate (PET), polybutylene terephthalate (PBT), and polylactic acid (PLA) polymer. The finished polymer may contact all food types under Condition of Use A-H.

Items containing 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: Facts and Figures 2015." The FCS will be used in both recyclable and non-recyclable polymers. Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities 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.

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 currently used.

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 8/19/19

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 environmental impact.

Consequently, we find that use of the FCS as a polymeric component of food-contact articles as described in FCN 1993, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 08-21-2019

Leah D. Proffitt

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 08-21-2019

Sarah C. Winfield

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