
Memorandum

Date: February 22, 2018

To: Anita Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Leah Proffitt, Acting Supervisor, Environmental Review Team, Office of Food Additive Safety (HFS- 255)

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

Subject: Finding of No Significant Impact for Food Contact Notification 1841 (Hexanedioic acid polymer with 1,3-benzenedimethanamine, CAS Reg. No. 25718-70-1)

Notifier: Mitsubishi Gas Chemical Company, Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1841, which is for the use of hexanedioic acid polymer with 1,3-benzenedimethanamine as the basic polymer in the manufacture of articles intended to contact food, except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated November 20, 2017, 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.

Sarah C. Winfield

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1841, submitted by Mitsubishi Gas Chemical Company, Inc. for the use of hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) as the basic polymer in the manufacture of articles intended to contact food. Articles containing the FCS may be used in contact with all types of food under Conditions of Use A through H.¹ The FCS may contain optional adjuvants permitted for use in nylon resins complying with 21 CFR 177.1500, subject to the prescribed limitations and specifications in the authorizing regulation or notification. 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 November 20, 2017. 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 polymer to make food contact materials. Once the FCS-containing food contact articles are made, they will be used and then disposed of as rubbish or recycling. We do not expect an impact to recycling, as good manufacturing practices of polymers include proper labeling of end use articles to inform both users and recyclers. The food contact articles made with the FCS that are not recycled will be disposed of in a landfill or incinerated. Based on confidential market volume information provided in a confidential attachment to the EA, the FCS will make up a very small portion of the total municipal solid waste (MSW) landfilled and incinerated (even when assuming none of the FCS is recycled, which overestimates the amount landfilled and incinerated).

Because of the Environmental Protection Agency's (EPA's) regulations governing landfills (40 CFR Part 258) and the marginal amount of the FCS that would be landfilled, the FCS is not expected to be introduced to land or water when disposed via landfill. Similarly, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS and the marginal amount of FCS compared to all combusted MSW). The EA also considered the impact of greenhouse gas (GHG) emissions in a confidential attachment. The EA confidential attachment estimates the total annual emissions of GHGs, represented as carbon dioxide-equivalent (CO₂-e) in metric tons (mT). The GHG estimate is 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 MSW combustion facilities. In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1841.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of the materials which the FCS would otherwise replace; such action would have no environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 2/14/18

As evaluated in the EA, the use of the FCS, as described in FCN 1841, as a basic polymer used in the manufacture of articles intended to contact food, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 02-22-2018

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 02-22-2018

Leah Proffitt

Acting Supervisor, Environmental Review Team

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