U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 30, 2017

To: Elizabeth Furukawa, Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Biologist, Office of Food Additive Safety, HFS-255

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

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1840 for 1,4-Benzenedicarboxylic acid, polymer with 1,4-cyclohexanedimethanol, 1,2-ethanediol, [4-(hydroxymethyl)cyclohexyl]methyl 4-(hydroxymethyl)cyclohexanecarboxylate, 2,2'-oxybis[ethanol] and 4,4'-[oxybis(methylene)]bis[cyclohexanemethanol], CAS Reg. No. 1632972-01-0.

Notifier: SK Chemicals, Co., Ltd.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1840 for 1,4-Benzenedicarboxylic acid, polymer with 1,4-cyclohexanedimethanol, 1,2-ethanediol, [4-(hydroxymethyl)cyclohexyl]methyl 4-(hydroxymethyl)cyclohexanecarboxylate, 2,2'-oxybis[ethanol] and 4,4'-[oxybis(methylene)]bis[cyclohexanemethanol], CAS Reg. No. 1632972-01-0, as a polymeric component of food-contact articles, except for use in contact with infant formula and human milk, under Conditions of Use C through G.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated November 17, 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

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1840), submitted by SK Chemicals, Co., Ltd., to provide for the safe use of 1,4-Benzenedicarboxylic acid, polymer with 1,4-cyclohexanedimethanol, 1,2-ethanediol, [4-(hydroxymethyl)cyclohexyl]methyl 4-(hydroxymethyl)cyclohexanecarboxylate, 2,2'-oxybis[ethanol] and 4,4'-[oxybis(methylene)]bis[cyclohexanemethanol], CAS Reg. No. 1632972-01-0, as a polymeric component of food-contact articles, except for use in contact with infant formula and human milk, under Conditions of Use C through G.

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, dated November 17, 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.

When combined with polyesters, the FCS produces desirable properties such as thermal stability, versatility and flexibility. 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 2014." Since the FCS is intended to be used with polyolefins, recycling is also expected to occur in proportion to national figures reflected in the EPA report. 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. Market volume information provided in a confidential attachment to the EA demonstrates that the FCS will comprise a very small portion of MSW, compared to overall MSW generated; this comparison uses EPA's 2014 MSW statistics.

According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), including nitrous oxide (N2O), 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 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 packaging articles will consume energy and resources in amounts comparable to the manufacture and use of materials currently used.

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 1840, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 11-30-2017
Leah D. Proffitt
Acting Environmental Supervisor
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-11-2017
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