

Memorandum

Date: April 18, 2019

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

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

From: Chemist, Division of Food Contact Notifications, HFS-275

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1963 for fatty acids, C14-C20, esters with pentaerythritol (PEFAE, CAS Reg. No. 68440-28-8).

Notifier: Peter Greven GmbH & Co. KG.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1963, which is for the use of fatty acids, C14-C20, esters with pentaerythritol as a processing agent at a level not to exceed (NTE) 2 wt.-% in poly(ethylene terephthalate) (PET) and poly(butylene terephthalate) (PBT) used in contact with food under Conditions of Use (COU) B-G. The FCS is not intended for use in contact with infant formula or human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated March 28, 2019, 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.

Daniel Chan, Ph. D.

Attachments:

Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN 1963) was submitted by Ecolab Inc., for the use of fatty acids, C14-C20, esters with pentaerythritol as a processing agent at a level not to exceed (NTE) 2 wt.-% in poly(ethylene terephthalate) (PET) and poly(butylene terephthalate) (PBT) used in contact with food under COU B-G. ¹ The FCS is not intended for use in contact with infant formula or human milk.

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 March 28, 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.

Manufacture of the FCS is not expected to result in significant environmental impact. Manufacture of food-contact articles containing the FCS is also not expected to result in a significant impact to the environment. Items containing the FCS are expected to be land disposed, combusted, or recycled proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2015 Fact Sheet." 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, as compared to overall MSW generated; this comparison uses EPA's 2015 MSW statistics. According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases 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.

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 those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (i.e., similar processing aids already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS are 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 04/01/2019

Consequently, we find that use of the FCS as a processing aid in the production of PET and PBT polymers as described in FCN 1963 will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed on 04-18-2019

Daniel Chan

Chemist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed on 04-18-2019

Leah Proffitt

Biologist

Environmental Review Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration