U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 28, 2020

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

To: K. McAdams, M.S., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 2069 (pentaerythritol (CAS Reg. No. 115-77-5)).

Notifier: Kaneka North America, LLC.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 2069, which is for the use of pentaerythritol as a nucleating agent at levels not to exceed 1 weight percent in the manufacture of poly((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyhexanoic acid)) (PHBH). Food contact materials containing pentaerythritol in PHBH will be used under of Use E-G in contact with all foods except high alcohol foods, infant formula and human milk.

After this notification becomes effective, copies of this FONSI, an environmental assessment (EA) revision sheet, and the notifier's environmental assessment, dated May 15, 2020, may be made available to the public. We will post digital transcriptions of the FONSI, EA revision sheet 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

Attachments: Finding of No Significant Impact; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2069, submitted by Keller and Heckman LLP., on behalf of Kaneka North America LLC., for the use of pentaerythritol as a nucleating agent at levels not to exceed 1 weight percent in the manufacture of poly((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyhexanoic acid)). Food contact materials containing pentaerythritol in PHBH will be used under Conditions of Use E-G in contact with all foods except high alcohol foods, infant formula and 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 May 15, 2020. 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 as the FCS is anticipated to be entirely incorporated into the finished food-contact article. Food-contact articles containing the FCS are anticipated to be disposed of through landfilling or combustion in municipal solid waste (MSW) incinerators. When landfilled, the EA explains no environmental introduction is expected per 40 CFR 258, the regulations governing landfills. When combusted, the EA explains 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).

The EA also considered the impact of greenhouse gas (GHG) emissions. However, based on estimated market volume information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of the FCS per FCN 2069, is below 25,000 metric tons CO2-e, the U. S. EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, significant impacts to the environment are not anticipated.

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.

The use of the FCS, as described in FCN 2069, as a nucleating agent in the manufacture of PHBH, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 07-28-2020
Daniel Chan
Chemist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition, Food and Drug Administration

Approved by _____Date: digitally signed 07-28-2020
Mariellen Pfeil
Supervisory Biologist
Environmental Review Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition
Food and Drug Administration

U.S. Food and Drug Administration
Revision Sheet for the May 15, 2020 EA for FCN 2069

The U.S. Food and Drug Administration (FDA) in its review of the May 15th, 2020 dated Environmental Assessment (EA) for food contact notification (FCN) 2069 concluded that the action will not constitute a significant impact. This revision is issued to make several minor changes and updates, of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revisions are necessary to explain/clarify the following:

- In describing the notified conditions of use (COU) (EA section 4, page 1, 2nd paragraph) the notifier omits a reference citation for the FDA COUs.

  This citation is *https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances*

- In EA section 4, page 2 (2nd paragraph) the notifier mentions PHA polymers but does not define the acronym.

  To clarify the identity of this material, this sentence is revised to:
  Food-contact materials containing the FCS may ultimately be subject to composting because polyhydroxyalkanoates (PHA) bioplastics, which include PHBH plastics, are biodegradable, readily compostable thermoplastics (https://www.plasticstoday.com/packaging/pha-bioplastics-tunable-solution-convenience-food-packaging/157388153458558).

- The notifier's analysis of impacts to resources and energy resulting from the use of the FCS in food contact polymers (EA section 9, page 5) is confusing.

  To clarify this analysis, this section is revised to:
  As is the case with other food-contact materials, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. Manufacture of the FCS, its use in PHBH polymers, and the final conversion to finished food-contact articles and packaging will consume energy and resources in amounts comparable to the manufacture and use of these food contact articles using other nucleating agents, which the FCS is intended to replace.

  Articles and packaging materials produced from PHBH containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. PHBH polymers (containing the FCS) are not expected to be recycled. However, if recycled, they would not impact recycling programs because PHBH articles would be removed from the recycling stream by source control procedures such as resin identification coding[1], and near-infrared sorting systems.[2]

[1]ASTM D7611 / D7611M – 20 Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, as described at https://vangelinc.com/astm-revises-resin-identification-code-symbol/

[2] NatureWorks LLC, "Using Near-Infrared Sorting to Recycle PLA Bottles," at: http://www.natureworksllc.com/~/media/The_Ingeo_Journey/EndofLife_Options/mech_recycling/20090708_NatureWorks_UsingNIRSortingtoRecyclePLABottles_pdf.pdf , detailing a method for sorting biopolymers from traditional plastic resins .