

Memorandum

Date: April 24, 2019

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

Through: Leah D. Proffitt, Biologist, 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 1967 (2,2-bis((pentanoyloxy)methyl)propane-1,3-diyl dipentanoate, CAS Reg. No. 15834-04-5)

Notifier: Perstorp AB

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1967, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1967 is 2,2-bis((pentanoyloxy)methyl)propane-1,3-diyl dipentanoate. The FCS is intended for use as a plasticizer in polyvinyl chloride (PVC) polymers for use at levels up to 31% in (1) repeated-use articles; (2) as a coating or component of paper or paperboard; (3) adhesives complying with 21 CFR 175.105; and (4) pressure-sensitive adhesives complying with 21 CFR 175.125. The FCS is not intended 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.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated March 21, 2019, may be made available to the public. We will post digital transcriptions of the FONSI, 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.

Sarah C. Winfield

Attachments:

Finding of No Significant Impact

EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1967, submitted by Perstorp AB for the use of 2,2-bis((pentanoyloxy)methyl)propane-1,3-diyl dipentanoate (CAS Reg. No. 15834-04-5), when used as a plasticizer in polyvinyl chloride (PVC) polymers for use in (1) repeated-use articles; (2) as a coating or component of paper or paperboard; (3) adhesives complying with 21 CFR 175.105; and (4) pressure-sensitive adhesives complying with 21 CFR 175.125. The FCS will be used at levels up to 31% in the PVC polymers. The FCS may be used in repeat-use food contact articles in contact with all food types under Conditions of Use A-H as described in Table 1 and Table 2, respectively.¹ The FCS may be used as a component or coating of paper and paperboard in contact with Food Type VIII only and under Conditions of Use A-H. The FCS may be used in adhesives complying with 21 CFR 175.105 and pressure sensitive adhesives complying with 21 CFR 175.125 in contact with all food types. The finished food contact articles containing the FCS are 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 March 21, 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.

The FCS is intended for use as a plasticizer in polyvinyl chloride (PVC) polymers at levels up to 31%. Once the FCS-containing food contact articles are made, they will be used and then disposed (recycled, landfilled or combusted). We do not expect an impact to recycling, as the FCS is similar to existing FCSs and will be used in the same manner. Furthermore, based on municipal solid waste (MSW) data from the Environmental Protection Agency (EPA), we do not expect widespread recycling of PVC. The food contact articles made with the FCS that are not recycled will be disposed of in a landfill or combusted. Based on confidential market volume information provided in a confidential attachment to the EA, the FCS will make up a small portion of the total MSW landfilled and combusted (even when assuming none of the FCS is recycled, which may overestimate the amount landfilled and combusted). Because of the 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 the confidential attachment. The EA confidential attachment estimates the total annual emissions of GHGs, represented as carbon dioxide-equivalents (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 1967.

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 4/1/19

As evaluated in the EA, the use of the FCS, as described in FCN 1967, as a plasticizer at up to 31% in PVC polymers, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed on 04-24-2019

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 on 04-24-2019

Leah D. Proffitt

Biologist, Environmental Review Team

Office of Food Additive Safety

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Food and Drug Administration

U.S. Food and Drug Administration

Revision Sheet for the March 21, 2010 EA for FCN 1967

Dated: April 24, 2019

The U.S. Food and Drug Administration (FDA) in its review of the March 21, 2019 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1967 concluded that the action will not constitute a significant impact. The revisions are issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. These revisions do not impact our Finding of No Significant Impact (FONSI).

These revisions are necessary to clarify the following:

- On page 1, the EA describes the intended use of the FCS per FCN 1967. The EA describes 3 applications (rather than the 4 applications listed in the final regulatory language). This is because application 3 and 4 in the final regulatory language are combined into application 2 in the EA. Although the intended use is presented differently, they describe the same applications.
- Also on page 1 and related to the intended use, the EA states two different Conditions of Use ranges for the application of the FCS as a coating or component of paper or paperboard. First, the EA states the FCS is for use as:

*“a coating or component of paper or paperboard intended for use in contact with dry foods with no free surface fat or oil in contact with food as a component of food-contact articles in contact with all types of food under **Condition of Use B through H.**” [bold emphasis added]*

And two sentences later, describes the conditions for this application as:

“Conditions of Use A through H”

The final regulatory language for FCN 1967 describes the intended use as a coating or component of paper or paperboard (p/pb) under Conditions of Use A-H, therefore, the correct range of conditions of use for coatings/components of p/pb are Conditions of Use A through H (and not B through H).

- On page 4, the EA states:

“Consequently, the proposed use of the FCS is expected to have no adverse impact on current or future recycling programs.”

As discussed in the FONSI, we do not expect an impact on recycling. Our finding of no significant impact to recycling is limited to current recycling programs. Predicting a theoretical impact to future recycling programs (from this FCN becoming effective) is considered beyond the scope of the EA.