
Memorandum

Date: June 30, 2020

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

To: Jacqueline Heilman, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2055: Ethylene glycol dipalmitate (CAS Reg. No. 624-03-3).

Notifier: Emery Oleochemicals GmbH

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2055, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2055 is for the use of ethylene glycol dipalmitate as a processing aid in rigid polyvinyl chloride (PVC), polycarbonate (PC), and polylactic acid (PLA), except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's EA dated May 25, 2020 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.

Denis Wafula, digitally signed 06-30-2020

Attachments: FONSI; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2055, submitted by Emery Oleochemicals GmbH for the use of ethylene glycol dipalmitate (CAS Reg. No. 624-03-3), as processing aid in rigid polyvinyl chloride (PVC), polycarbonate (PC), and polylactic acid (PLA). The FCS will be used in rigid PVC at levels up to 0.4 percent by weight in the finished article. In PC and PLA, the FCS will be used at levels up to 0.2 percent by weight in the finished article. Articles made from rigid PVC and PC will contact all food types under Conditions of Use (CoU) C through G. Articles made from PLA will contact all food types under CoU E through G as described in Tables 1 and 2 (<https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>, accessed 6/12/2020). 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.

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 25, 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.

The FCS is intended for use as a processing aid in rigid PVC, PC, and PLA. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. Significant recycling of finished articles is not anticipated. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Due to EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. Per information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO₂-equivalent (CO₂-e) in metric tons (mT), will not exceed 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 MWC facilities. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be the continued use of currently approved food-contact substances that the FCS would have replaced. Such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2055 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 06-30-2020
Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 06-30-2020
Mariellen Pfeil
Lead Biologist, Environmental 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 25, 2020 EA for FCN 2055

June 30, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of May 25, 2020 for food contact notification (FCN) 2055 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction 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 revision is necessary to make or explain changes that;

- Align the intended use of the FCS as stated in the EA with the final regulatory listing
- Provide information regarding the molecular weight of the FCS
- Clarify the information provided in 'Fig. 1: U.S. Polyvinyl Chloride Production Volume (1990-2018)'

Under Item 3) Description of the Proposed Action, the EA states:

'Articles made from PVC and PC will contact all food types under FDA's Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage"). Articles made from PLA will contact food types under FDA's Conditions of Use D (Hot filled or pasteurized below 66 °C (150 °F) through H (Frozen or refrigerated storage; ready prepared foods intended to be reheated in container at time of use.).'

We note that the **regulatory listing** of the FCN states that the Limitations/Specifications of the FCS are '... Articles made from rigid PVC and PC will contact all food types under Conditions of Use (CoU) C through G. Articles made from PLA will contact all food types under CoU E through G.'

Therefore, this sentence is revised to:

'Articles made from PVC and PC will contact all food types under FDA's Conditions of Use C through G. Articles made from PLA will contact food types under FDA's Conditions of Use E through G.'

Under Item 4.) Identification of Substance that is the Subject of the Proposed Action:

The molecular weight of the FCS (538.9 g/mol) should be provided.

Under Item 6.) Fate of Emitted Substances in the Environment:

The text box in the Figure 1 showing the production volume of PVC in 2016 does not contain any information relevant to the EA and should be disregarded.