Memorandum

Date: May 30, 2018

To: Vivian Gilliam, Division of Food Contact Notifications (HFS-275)

From: Supervisory Biologist, Env. Rev. Team, Office of Food Additive Safety, HFS-255

Subject: Finding of No Significant Impact for Food-Contact Notification (FCN) 1880 for 1,3-Benzenedicarboxamide, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- (CAS Reg. No. 42774-15-2).

Notifier: Clariant Plastics & Coatings USA Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1880 for use of 1,3-Benzenedicarboxamide, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- (CAS Reg. No. 42774-15-2), as a processing stabilizer in polyamide polymers complying with applicable authorizations, except for use in contact with infant formula and human milk. The Food Contact Substance (FCS) is intended for use at levels up to 0.5% in polyamide food-contact films not exceeding a thickness of 100 µm. The finished food-contact articles containing the FCS may be used under FDA Conditions of Use A through H.

After this notification becomes effective, copies of this FONSI and the notifier's EA, dated February 9, 2018 (as amended by FDA on 4/3/2018), 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: A food-contact notification (FCN No. 1880), submitted by Clariant Plastics & Coatings USA Inc., to provide for the safe use of 1,3-Benzenedicarboxamide, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- (CAS Reg. No. 42774-15-2) as a processing stabilizer in polyamide polymers complying with applicable authorizations, except for use in contact with infant formula and human milk. The Food Contact Substance (FCS) is intended for use at levels up to 0.5% in polyamide food-contact films not exceeding a thickness of 100 µm. The finished food-contact articles containing the FCS may be used under FDA Conditions of Use A through H.

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 February 9, 2018 (as amended by FDA on 4/3/2018). 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.
The Food Contact Substance (FCS) provides improvements (e.g., enhances the stability of the polymer melt pressure) in melt processing operations for polyamides. Additionally, the FCS boosts the UV stability of the polymer. Disposal of

articles manufactured with the FCS will be nationwide and will be via municipal solid waste (MSW) landfill (in compliance with 40 CFR 248) or incineration. Recycling is not anticipated. Based on confidential market volume estimates, emissions from MSW combustion facilities will not cause facilities to violate existing emissions regulations (40 CFR 60) or the mandatory greenhouse gas emissions reporting threshold (40 CFR 98.2). Environmental introduction of the FCS to surface waters as a result of dietary consumption of FCS migrants in food are not anticipated to exceed ecotoxicity endpoints for fish, *Daphnia* or algae. Therefore, no significant environmental introductions of the FCS are anticipated as a result of the use and disposal of articles manufactured with the FCS. As such mitigation measures are not required.

The use of this FCS is not anticipated to result in a net increase in the use of energy or resources, as the FCS is intended for use in finished polyamide films which will be used in place of other such films. The alternative of not approving the action proposed herein would simply be the continued use of such materials; such action would have no environmental impact.

Consequently, we find that use of the FCS as a stabilizer in polyamide polymers, as described in FCN 1880, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 05-30-2018
Mariellen Pfeil
Supervisory Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration