

Memorandum

Date: June 26, 2018

To: Marla Swain, Ph.D., 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

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1876 (Fluorophlogopite-based pearlescent pigments)

Notifier: Eckart GmbH
Altana AG

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1876, 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 1876 is fluorophlogopite-based pearlescent pigments. The FCS is intended for use as a colorant at levels up to 5% by weight in all food contact polymers, used with all food types under Conditions of Use A through H and J, as described in Tables 1 and 2, respectively. The FCS is 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.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated April 20, 2018, 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
Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1876, submitted by Eckart GmbH and Altana AG for the use of fluorophlogopite-based pearlescent pigments as a colorant in all food contact polymers, for use at levels up to 5% by weight in polymers in contact with all food types under Conditions of Use A through H and J, as described in Tables 1 and 2, respectively.¹ The FCS is 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 April 20, 2018. 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 colorant in food contact polymers. Once the FCS-containing food contact articles are made, they will be used and then disposed. We do not expect FCS-containing food contact articles to be recycled, but rather disposed of in a landfill or incinerated. Based on confidential market volume information provided in a confidential attachment to the EA, the FCS will make up a very small portion of the total municipal solid waste (MSW) landfilled and incinerated. Because of the Environmental Protection Agency's (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. When incinerated, since the FCS is not combustible, no environmental introduction to the air is expected. In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1876.

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.

As evaluated in the EA, the use of the FCS, as described in FCN 1876, as a colorant for polymers used in the manufacture of articles intended to contact food, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: Digitally signed 6/26/2018

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 6/26/2018

Mariellen Pfeil
Supervisory Biologist, Environmental Review Team
Office of Food Additive Safety
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Food and Drug Administration

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 6/21/18

U.S. Food and Drug Administration**Revision Sheet for the April 20, 2018 EA for FCN 1876****Dated: June 26, 2018**

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of April 20, 2018 for Food Contact Substance Notification (FCN) 1876 concluded that the action will not constitute a significant impact. The revision is 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. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

- Under Section 7 (b) the EA states “as demonstrated by the solubility studies that have been carried out.” However, no solubility studies were cited to support this statement. We understand the FCS is insoluble based on the nature of the FCS and Reference 2 under Section 14: Becker et. al “Safety Assessment of Synthetic Fluorophlogopite as Used in Cosmetics.” International Journal of Toxicology, 2015, Vol 23 (Supplement 3).
- Between Section 11 “Alternatives to the Proposed Action” and Section 12 “Certification, there is an un-numbered section titled “List of Preparers.” Following Section 12 is Section 14 “References.” Section 13 is not missing from the EA, but rather a formatting error. The “List of Preparers” section should be numbered “12,” the “Certification” section should be numbered “13,” and then the “References” section would follow as number “14.”