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## Memorandum

**Date:** February 12, 2020

**To:** Sean Fischer, 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)

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

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2117: fluorophlogopite-based pearlescent pigment for use in food-contact applications.

**Notifier:** EMD Performance Materials Corporation

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2117, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2117 is for the use of a fluorophlogopite-based pearlescent pigment.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA) dated December 7, 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.

Brittany Ott

Attachment:

Finding of No Significant Impact (FONSI)

## FINDING OF NO SIGNIFICANT IMPACT

**Proposed Action:** Food Contact Notification (FCN) 2117, submitted by EMD Performance Materials Corporation for the use of the Food Contact Substance (FCS) fluorophlogopite-based pearlescent pigment as specified below.

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 December 7, 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 for use as a colorant in all food-contact polymers, at levels not to exceed 5% weight for single and repeat-use articles, including disposable food-contact materials such as utensils and serving ware and will be used under Conditions of Use A (“High temperature heat-sterilized (e.g. over 212°F)”) through H (“Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use”). This FCS will not, however, be for use in contact with infant formula and human milk, and as such these uses were not included as part of the intended use of the substance in the FCN.

Items manufactured with the FCS are expected to be land disposed, combusted or recycled proportionately with disposal patterns described in the U.S. Environmental Protection Agency’s (EPA) report, *Advancing Sustainable Materials Management: 2017 Fact Sheet*.<sup>1</sup> Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. Mineral pigments, such as the FCS, are common in recycled polymers. Therefore, impacts to recycling are not anticipated.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be 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.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use and are not expected to significantly impact waste streams. No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

The FCS is a relatively high molecular weight polymer and is therefore inherently non-volatile. Additionally, the polymeric nature of the FCS is expected to result in virtually no leaching of the FCS components under normal environmental conditions when articles containing the FCS are disposed in sanitary landfills. As such, no adverse effect on organisms in the environment is expected as a result of the FCS disposal. Further, the low production volume of food-contact articles containing the FCS precludes any substantial release of its components to the environment.

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<sup>1</sup> We note that in Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA. Please see the following links:

- [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf)
- [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf)

We note that this report does not impact the conclusions presented in the EA, so no revision was required. However, the notifier was advised to utilize these reports in their future submissions.

[www.fda.gov](http://www.fda.gov)

As evaluated in the EA, the proposed use of the FCS as described in FCN 2117 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by \_\_\_\_\_ Date: digitally signed 02-12-2021

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Approved by \_\_\_\_\_ Date: digitally signed 02-18-2021

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