

Environmental Assessment

1. **Date:** December 7, 2020
2. **Name of Applicant/Petitioner:** Merck KGaA, Darmstadt, Germany and its affiliated companies
3. **Address:** All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. **Description of Proposed Action**

A. **Requested Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), identified as fluorophlogopite-based pearlescent pigments, when used in food-contact materials.

The FCS is intended for use as a colorant for all food-contact polymers, for use at up to 5% by weight in the polymers. Food-contact articles containing the FCS may 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: Ready prepared foods intended to be reheated in container at time of use") and J ("Cooking at temperatures exceeding 250°F").¹ The finished food-contact materials containing the FCS are not for use in contact with infant formula and human milk, as these uses were not included as part of the intended use of the FCS.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to food-contact polymer and article manufacturers.

B. **Need for Action**

The FCS is intended to be used as a colorant for polymers that will be used in food-contact materials. The FCS serves to provide color and a pleasing visual appearance to polymeric food-contact articles. The food-contact articles include food packing and repeat-use articles, as well as disposable food-contact materials such as utensils and serving ware.

¹ FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2017, approximately 52.1% of municipal solid waste is currently deposited in land disposal sites, 12.7% is combusted with energy recovery, 25.1% is recycled, and 10.1% is composted.² The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the polymeric resins in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is synthetic fluorphlogopite-based pearlescent pigments, which exist as powders to be used as colorants for polymers. The finished fluorphlogopite-based pigments do not have a Chemical Abstracts Service (CAS) Registry Number. Physically, the pigments consist of fluorphlogopite flakes (*i.e.* as the substrate/carrier; CAS Reg. No. 12003-38-2) coated with insoluble metal oxide layers (*i.e.*, oxides of titanium, tin, aluminum, and/or other cleared inorganic oxides) on the fluorphlogopite surface. Fluorphlogopite is an analogue of mica (potassium aluminum silicate) in which some of the hydroxyl ions on the aluminum atom have been replaced by fluorine ions. The chemical formula of fluorphlogopite is $Mg_3K[AlF_2O(SiO_3)_3]$ with a molecular weight of 421.2 g/mol. The pearlescent pigments are prepared by calcining titanium, tin, aluminum, or other inorganic salts into insoluble metal oxides on the fluorphlogopite substrate.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS is expected to be entirely incorporated into finished materials, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste material generated during

² *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, available at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to this report, of the total 268 million tons of municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted with energy recovery, 25.1% is recycled, and 10.1% is composted.

the manufacture of the finished articles, *e.g.*, plant scraps, is expected to be disposed as part of the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or to a minor extent, recovery for recycling.

The FCS is a complex matrix of inorganic coated fluorphlogopite, formed at high temperatures, and contains tin, titanium, aluminum, and/or other inorganic oxides. The FCS is inorganic and not combustible, and thus, no airborne emission products are expected to be released into the environment upon incineration of food-contact materials which contain the FCS.

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the U.S. EPA under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that, when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, when materials containing the FCS are combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60 and 62 (as it is inorganic and not combustible). As such, no significant environmental impacts are anticipated resulting from combustion of articles containing the FCS in MSW combustion facilities.

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and

leachate collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. As discussed under Item 6, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations.

B. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS. The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

C. Land

Considering the factors discussed above, no significant effects on the concentration of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS.

Considering the foregoing, the environmental fate does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS was identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, we do not expect the FCS to be released to the environment. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS as a colorant for polymers is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of food-contact materials in which similar products that are already on the market (*i.e.*, pigments and other colorants for polymers) are used. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Food-contact materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used materials with or without comparable colorants.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated with the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No significant adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the dyes, pigments, and other colorants for polymers that the subject FCS would replace (*i.e.*, the colorants for polymers cleared under 21 C.F.R 178.3297 (“Colorants for polymers”)), and other similar pigments cleared *via* Food Contact Notification). Such action would have no significant environmental impact.

12. List of Preparers

1. Pamela L. Langhorn, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Langhorn has over 20 years of experience counseling and representing corporate entities on Food Contact Notifications, including Environmental Assessments.
2. Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Manning has over 4 years of experience preparing Food Contact Notifications, including Environmental Assessments.
3. Ryan M. Bain, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Bain has nearly a year of experience preparing Food Contact Notifications, including Environmental Assessments.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: December 7, 2020



Pamela L. Langhorn
Counsel for Merck KGaA, Darmstadt, Germany
(EMD Performance Materials)

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.
2. *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, available at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf.

15. Attachments

None