

Environmental Assessment

1. **Date:** November 11, 2022
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 aluminum oxide Al₂O₃, when used in food-contact materials.

The FCS is intended for use as a component of inorganic pigments in combination with other authorized inorganic substances where the FCS will function as (1) a substrate for the inorganic pigment; and/or (2) a coating component for the inorganic pigment. When the FCS is used as the substrate, the pigments consist of aluminum oxide flakes coated with inorganic colorant components, such as titanium, iron, tin and/or silicon oxides. When the FCS is used as a component of inorganic coatings for pigments, it will be deposited onto inorganic substrates. The finished pigment containing the FCS is intended for use as a colorant in printing inks for food-contact articles. 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.

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>.

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 article manufacturers.

B. Need for Action

The FCS is intended to be used in the production of colorants in printing inks that will in turn be used in food-contact materials. The FCS serves to provide color and a pleasing visual appearance to the printing inks and the food-contact materials onto which the inks are applied. The food-contact articles include food packing and repeat-use articles, as well as disposable food-contact materials such as utensils and serving ware.

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 2018, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting), and 6.1% is directed to other food management pathways.² The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is aluminum oxide, Al₂O₃ (CAS Reg. No. 1344-28-1). The FCS may be used as a component of inorganic pigments in combination with other authorized inorganic substances where the FCS will function as (1) the substrate for the inorganic pigment; and/or (2) a coating component for the inorganic pigment. The inorganic pigment containing the FCS will be used as a colorant in printing inks.

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.

² *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

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 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 aluminum oxide, Al₂O₃, an inorganic metal oxide, also known as alumina. 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.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements 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.

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.

EPA's regulations require all solid-waste 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 and Appendix 2). These requirements are enforced by solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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 in printing inks 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 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 printing inks that the subject FCS would replace (*e.g.*, the colorants for polymers and paper and paperboard authorized under 21 C.F.R. §§ 178.3297 (“Colorants for polymers”) and 176.170 (“Components of paper and paperboard in contact with aqueous and fatty foods”), respectively, and other similar pigments authorized *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, D.C. 20001. Ms. Langhorn has over 23 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, D.C. 20001. Dr. Manning has 6 years 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: November 11, 2022



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: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Attachments

None