Environmental Assessment

1. Date: August 28, 2025*

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4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), aluminum magnesium carbonate hydroxide (quintinite), surface-treated with cis-1,2-cyclohexanedicarboxylic acid. The FCS is intended for use as a nucleating agent and acid scavenger in polyolefins at levels of up to 2,000 parts per million (ppm) in polyolefins in contact with all types of food under FDA's Conditions of Use A through H. The FCS is not intended 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 Notifier does not produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.[1] According to U.S.

[1] *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, Dec. 2020, *see* Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

* Subsequent to this date, this EA was edited using the Adobe Acrobat direct edit tool to align the EA's description of the action with the notification regulatory language.

Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[2] As food-contact materials containing the FCS are expected to be primarily disposed of through combustion, recycling, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.[3]

5. Identification of the Substance that is the Subject of the Proposed Action

Chemical Name: Aluminum magnesium carbonate hydroxide (quintinite) surface treated with *cis*-1,2-cyclohexanedicarboxylic acid, as described in the Notification.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), 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 food-contact materials. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the FCS in food-contact materials. In these applications, the FCS (*i.e.*, an additive for polyolefins) is expected to be entirely incorporated into the finished food-contact materials. Any waste materials generated in this process, *e.g.,* plant scraps, are expected to be disposed of as part of the food-contact material manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by recycling or conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact materials containing the FCS that are determined to be recyclable, recycling

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[2] *Id.*

[3] 11.8% Combusted ÷ (11.8% Combusted + 23.6% Recycled + 50% Land Disposed) = 13.8% Combusted.

processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

The subject FCS consists of the elements magnesium, aluminum, carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. The carbon content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the confidential attachment to the EA).[4] The potential GHG emissions are below 25,000 metric tons carbon dioxide equivalent (CO2-e) emission per MSW combustor (MSWC) on an annual basis.[5] Thus, the concentration of GHG in the environment will not be significantly altered by the proper incineration of the polymers containing the FCS in the amounts utilized for food packaging applications. Furthermore, 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 (*i.e.*, 40 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 CFR 98, "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO2-e threshold for required reporting (40 CFR 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 CFR 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of polymers containing the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

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 materials, 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 CFR Part 258)." These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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4 Provided in a confidential addendum to the Environmental Assessment.

5 U.S. estimated 75 MSWCs. See US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), available at https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from solid waste combustion facilities operating under 40 C.F.R. Part 60.

As indicated above in Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. *See* **Attachment 14** Confidential Addendum to the Environmental Assessment for additional details.

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact articles containing 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 concentrations of and exposures to any substances in terrestrial ecosystems are anticipated because of the proposed use of the subject FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the subject FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment because of the use and disposal of food-contact materials containing the FCS in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS is intended to be used in food-contact resins in place of other nucleating agents or acid scavengers currently on the market.

The replacement of other products by the subject FCS in food-contact resins is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use other products. Packaging materials produced from resins containing the FCS are expected to be disposed of according to the same patterns when they it is used in place of current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the subject FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in the Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the material that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Kathryn Skaggs, JD, MPH (Epidemiology and Biostatistics), Partner, Keller and Heckman LLP 1001 G Street NW, Suite 500W, Washington, DC 20001. Ms. Skaggs has 14 years of experience with Environmental Assessments for FDA submissions.

Kristin P. Wiglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Wiglesworth has over 8 years of experience performing evaluations relating to all aspects of preparing FCNs and 19 years of total experience in FDA regulated industries.

13. Certification

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

Date: August 28, 2025

Kathryn C. Skaggs
Counsel for Notifier

14. References

1. Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations, Appendix V, Table 2: Conditions of Use. Available at*:* *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081818.htm*.

2. *Advancing Sustainable Materials Management: 2018 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 2020, available at: *https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf*.

15. Attachment

1. Confidential Addendum to the Environmental Assessment – **Attachment 14**