ENVIRONMENTAL ASSESSMENT

1. Date: August 22, 2024

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4. Description of the Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3), when used in food-contact materials. The FCS is intended for use as an antioxidant/stabilizer in ethylene-methyl acrylate (EMA) copolymer resins complying with 21 C.F.R. § 177.1340 at levels not to exceed 0.1 percent by weight of the finished article, for use as a component of food-contact articles intended to contact all food types, except infant formula and human milk, 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").[1]

[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.

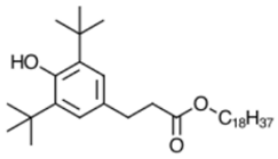
B. Need for Action

The FCS is intended to be used as an antioxidant in polymeric food-contact materials. The FCS inhibits oxidation, and thus deterioration of technical performance, of polymers used in food-contact materials.

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 of the FCS will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2018, published in 2020, approximately 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[2] Assuming that food-contact materials made from EMA copolymers containing the FCS are primarily disposed of through combustion or land-filling (*i.e.*, not recycled, 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 19.1% of food-contact materials containing the FCS will be combusted annually.[3] The low use level of the FCS in food-contact materials is not expected to impact the disposal patterns of the polymeric resins in which it is used.

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

Chemical Abstracts Service (CAS) name:	Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate
CAS Registry Number:	2082-79-3
Chemical Formula:	$C_{35}H_{62}O_3$
Molecular Structure:	

[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 Resource Conservation and Recovery, December 2020, *available at:* https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] By assuming that none of the FCS is recycled, composted, or handled through other food management pathways, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% is assumed to be land-disposed.

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 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. 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 subject FCS as a component of food-contact materials. The FCS will be entirely incorporated into the finished food-contact materials, and is expected to remain with the food-contact materials throughout use in food-contact applications and use/disposal by the consumer. Any waste materials generated in the manufacture of food-contact materials, *e.g.*, plant scraps, are expected to be disposed of as part of the manufacturer's overall nonhazardous solid waste in accordance with established procedures.

The FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. 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[4] and is below 25,000 metric tons carbon dioxide equivalent (CO2-e) emission per MSW combustor (MSWC) on an annual basis.[5] Thus, the concentration of carbon dioxide in the environment will not be significantly altered by the proper incineration of 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 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.

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[4] Notifier. Confidential market volume data & greenhouse gas emissions calculation (Confidential Attachment to the EA provided for FDA review).

[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.

Only extremely small amounts, if any, of the FCS 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.

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, as the FCS does not readily volatilize. 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.[6] Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and 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 fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact materials manufactured with 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 as a result of the proposed use of the subject FCS. In particular, the chemical characteristics of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS,[7] precludes any substantial release to

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[6] Notifier. Confidential market volume data & greenhouse gas emissions calculation (Confidential Attachment to the EA provided for FDA review).

[7] *Ibid.*

the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of these substances as a result of the proposed use of the 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 FCS in the manufacture of food-contact materials. Therefore, the environmental fate of substances 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 were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, no significant releases of the FCS are expected to occur 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 food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency'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 packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products already being marketed (*i.e.*, antioxidants permitted for use in EMA polymers), as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles with or without comparable additives. Because the FCS is used at an exceedingly low level in the production of food-contact materials, there will be no significant impact on current or future recycling programs. Further, in addition to this FCS, other antioxidants are found in a variety of food-contact materials and recycled products.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials

that the subject FCS would otherwise replace; such action would have no anticipated environmental impact.

12. List of Preparers

Kathryn Skaggs, JD, MPH, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001. Ms. Skaggs has 13 years of experience with Environmental Assessments for FDA submissions.

Holly Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Foley has over 24 years of experience performing evaluations relating to all aspects of preparing FCNs, and 40 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 her knowledge.

Kathryn C. Skaggs
Counsel for Notifier
Date: August 22, 2024

14. 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 http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

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 Resource Conservation and Recovery, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Attachments

1. Confidential Attachment to Environmental Assessment.