Environmental Assessment

1. Date: August 22, 2025

2. Name of Applicant/Notifier: Clariant Corporation

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action

The action requested in this notification is to provide for the use of oxidized rice bran wax (CAS Reg. No. 1883583-80-9) and its calcium salt (CAS Reg. No. 1850357-57-1) as a processing aid, lubricant, release agent, or slip additive in rigid polyvinyl chloride that contacts all types of food. The Food Contact Substance (FCS) is intended for use at levels up to 0.5% in rigid polyvinyl chloride. Rigid polyvinyl chloride containing the FCS is intended to be used in contact with all food types, except foods for infants, under FDA's Conditions of Use B ("Boiling water sterilized.") through H ("Frozen or refrigerated storage: Ready prepared foods intended to be reheated in container at time of use").[1]

The Notifier does not intend to produce finished food-contact articles from the FCS. The FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles containing the FCS will be used 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.[2] The U.S. Environmental Protection Agency (EPA) reports that, based on 2018 data, approximately 50.0%

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[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, Dec. 2020*; available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

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%, which is food waste, is directed to other food management pathways.[3] Food-contact articles containing the subject FCS cannot be composted and, therefore, will be disposed of only through recycling, combustion, or land-filling. The percentage of food-contact articles containing the FCS that will be combusted is recalculated based on this more limited disposal pattern and will not exceed 13.8%.[4]

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

Native rice bran wax is a hard crystalline vegetable wax processed from rice bran oil obtained from rice husks. The FCS that is the subject of this notification is partially oxidized rice bran wax (CAS Reg. No. 1883583-80-9) and its calcium salt (CAS Reg. No. 1850357-57-1). The FCS is a mixture of unoxidized rice bran wax esters, very long-chain aliphatic fatty acids derived from partial oxidation of native rice bran wax esters, and a small fraction of residual wax alcohols.

6. Introduction of Substances into the Environment

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 (21 C.F.R. § 25.40(a)). The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate a potential for adverse environmental impacts resulting from the manufacture of the FCS. Consequentially, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

No environmental release is expected upon the use of the subject FCS to fabricate packaging materials. The FCS will be entirely incorporated into the finished food-contact articles in these applications. Any waste materials generated in this process (*e.g.*, plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal of food-contact materials containing the subject FCS by the ultimate consumer will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. Food-contact articles containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste is currently deposited in land disposal sites, 11.8% is combusted with energy

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[3] *Id.*

[4] 11.8% Combusted ÷ (11.8% Combusted + 23.6% Recycled + 50% Land Disposed) = 13.8% Combusted.

recovery, 23.6% is recycled, and 8.5% is composted.[5] The use of the FCS in food-contact articles will not impact the disposal patterns of the articles in which it is used.

These disposal patterns are recalculated here based on only the quantities of municipal solid waste (MSW) that are land disposed or combusted because, although the FCS is recyclable, current waste infrastructure does not fully support its recycling. Therefore, approximately 19.1% of food packaging materials containing the FCS will be combusted annually. This amount is estimated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. Therefore, it is anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

The FCS is composed of carbon, oxygen, and hydrogen; elements that are commonly found in municipal solid waste. We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual MSW production (292 million tons MSW in 2018), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of packaging that contains the FCS. Further, the proposed use of the FCS and corresponding projected market volume (available in the Confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 11.8% of the 292 million tons total waste generated, or 34.5 million tons, as of 2018.[6] Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant municipal solid waste combustors, and incineration of food-contact articles containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

An analysis of the significance of environmental impacts should include the degree to which the action may violate relevant federal, state, or local laws imposed or policies designed for the protection of the environment in accordance with 40 C.F.R. § 1501.3(d)(2)(iii).[7] Title 40

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[5] *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).

[6] *Id.*

[7] 40 C.F.R. Parts 1500-1508 have been rescinded pursuant to a February 25, 2025 interim final rule issued by Council on Environmental Quality (CEQ). 90 Fed. Reg. 10,610 (Feb. 25, 2025) *available at* https://www.federalregister.gov/documents/2025/02/25/2025-03014/removal-of-national-environmental-policy-act-implementing-regulations. This EA references these rescinded regulations pursuant to FDA's existing NEPA implementing procedures provided in 21 C.F.R. § 25 and related guidance. *See* U.S. Food and Drug Admin., *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN*, May 2006 (current as of Sept. 20, 2018), *available at* https://www.fda.gov/regulatory-

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C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-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. Environmental Protection Agency (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. Subsection 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 (CO_2-e) emission threshold for required reporting.

The expected carbon dioxide emissions resulting from combustion of the FCS were estimated in the confidential attachment to the Environmental Assessment from the fifth-year confidential market projection. These expected emissions are far below 25,000 metric tons annually. No significant environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities because the estimated GHG emissions are far below the threshold for mandatory reporting.

Only extremely small amounts, if any, of the FCS are expected to enter the environment via landfill disposal of food-contact articles consequent to the EPA's regulations governing municipal solid waste landfills. EPA's regulations require new municipal 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 groundwater monitoring systems (40 C.F.R. Part 258).

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, because the FCS does not readily volatize. Thus, no significant quantities of any substances will be released to the air 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. Therefore, combustion of the FCS will not significantly alter the emissions from 40 C.F.R. § 60-compliant operating municipal solid waste combustors, and the incineration of

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information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan#III. CEQ has advised that "agencies should apply their current NEPA implementing procedures with any adjustments needed to be consistent with the NEPA statute as amended by the [Fiscal Responsibility Act]." Exec. Office of the President, CEQ, Chief of Staff, Katherine R. Scarlett, *Memorandum for Heads of Federal Departments and Agencies*, February 19, 2025, *available at* https://ceq.doe.gov/docs/ceq-regulations-and-guidance/CEQ-Memo-Implementation-of-NEPA-02.19.2025.pdf.

food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See the Confidential Attachment 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. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills.

Plant waxes, similar to rice bran wax, are produced in the epidermal cells of most plants and exuded onto the cell surface. Many plants also have a layer of cross-esterified hydroxy fatty acids called cutin on the surface of the epidermal cells that is impregnated with waxes. This combined lipid layer protects the plant from invasion by foreign organisms and assists in the regulation of transpiration.[8] Thus, plant waxes, and the components of plant waxes such as the associated fatty acids and fatty alcohols are ubiquitous in nature and are a part of human and animal diets. The extremely small or nonexistent environmental introduction concentrations associated with the disposal of packaging containing the FCS could not alter the natural background concentrations of plant waxes and their components in the environment.

C. Land

The factors discussed above support a conclusion that no significant effects on the concentration of and exposure to any substances in terrestrial ecosystems are anticipated due to the proposed use of the subject FCS. Virtually no leaching of FCS under normal environmental conditions is expected when finished food-contact materials fabricated using the FCS are landfill disposed. Furthermore, the low production of the FCS for use in food-contact applications precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances due to the proposed used of the FCS.

Considering the foregoing, no reasonable expectation exists 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 articles. Therefore, the environmental fate of substances does not need to be addressed because no significant introduction of substances into the environment due to the proposed use of the FCS were identified as discussed under Item 6.

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[8] P.E. Kolattukudy, K.E. Espelie, and R.W. Davis, *Composition, Ultrastructure and Function of the Cutin- and Suberin-Containing Layers in the Leaf, Fruit Peel, Juice-Sac and Inner Seed Coat of Grapefruit (Citrus paradisi Macfed.),* Planta, **149**, No. 5 (1980), pp. 498-511.

8. Environmental Effects of Released Substances

The only substances expected to be released into the environment upon the use and disposal of food packaging materials fabricated with the subject FCS are extremely small quantities of combustion products and leachables, if any. No reasonable expectation exists 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 articles. Thus, no significant adverse effect on organisms in the environment is expected from the use and disposal of food-contact materials containing the FCS. The use and disposal of the subject FCS 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. § 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

The production, use, and disposal of the FCS involves the use of natural resources such as petroleum products and coal as is the case with other food packaging materials. Manufacture of the FCS and its conversion to use in a finished food-contact polyester will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact materials. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject FCS, or from the minute amounts of the FCS that may migrate to food, be consumed, and subsequently disposed by sanitary sewer. This is primarily due to the minute levels of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products containing the 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 in this assessment that would necessitate alternative actions to that 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 significant environmental impact.

12. List of Preparers

George G. Misko, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Misko has over thirty-five years of experience in preparing, supervising the preparation of, and counseling corporate entities on Food Additive Petitions and Food Contact Notifications, including Environmental Assessments.

Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Hepp has more than twenty-six years of experience reviewing and/or preparing Food Additive Petitions and 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 his knowledge.

Date: August 22, 2025

George G. Misko
Counsel for Notifier

14. References

1. FDA's Food Types and Conditions of Use, accessed January 2022, at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. Advancing Sustainable Materials Management: Facts and Figures 2018, U.S. Environmental Protection Agency, accessed January 2022, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

3. P.E. Kolattukudy, K.E. Espelie, and R.W. Davis, *Composition, Ultrastructure and Function of the Cutin- and Suberin-Containing Layers in the Leaf, Fruit Peel, Juice-Sac and Inner Seed Coat of Grapefruit (Citrus paradisi Macfed.)*, Planta, **149**, No. 5 (1980), pp. 498-511.

15. Attachments

1. Confidential Attachment – Attachment 9