Environmental Assessment

1. Date: April 18, 2025 *

2. Name of Applicant/Petitioner: Kronos (US), Inc.

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All communications on this matter are to be sent in care of Counsel for Kronos (US), Inc.:

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4. Description of Proposed Action

a) Requested Action

The proposed action in this Food-Contact Substance Notification (FCN) is to permit the use of the following food-contact substance (FCS) as a colorant for polymers: *n*-octyl phosphonic acid (NOPA; CAS Reg. No. 4724-48-5)-modified titanium dioxide (CAS Reg. No. 13463-67-7). The FCS is produced by chemically reacting NOPA with titanium dioxide to achieve a maximum treatment level of 0.85% NOPA by weight of pigment, and is intended for use (1) at levels up to 20% by weight of polymer when the finished polymer is intended for use in contact with all food types under Conditions of Use A, B, and H; and (2) at levels up to 30% by weight of polymer when the finished polymer is intended for use in contact with all food types under Conditions of Use C through G. The FCS is not intended for use in contact with infant formula or human milk.

b) Need for Action

The FCS is intended to be used as a colorant for food-contact polymers. The addition of NOPA is intended to modify the surface of titanium dioxide and enhance its dispersibility when used as a colorant for food-contact polymers. The NOPA treatment also provides hydrophobic properties to the surface of the titanium dioxide pigment.

c) Locations of Use / Disposal

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials and articles. Food contact articles produced with the FCS in the U.S. 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 will occur nationwide.

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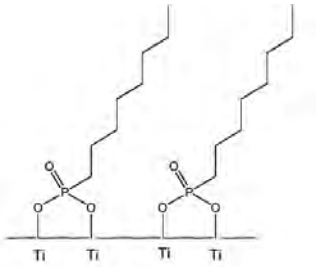
* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature.

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

The FCS is intended for use as a colorant in food-contact polymers. The structure of the modified TiO2 can be depicted generally as follows:



Unmodified titanium dioxide is authorized for use as a colorant in food-contact polymers under 21 C.F.R. § 178.3297 ("Colorants for polymers"). The FCS is currently cleared for use as a colorant in food-contact polymers under effective FCNs 38, 419, and 2279. The intended use of the FCS is expected to be substitutional for the uses of the FCS described in FCNs 38, 419, and 2279.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an environmental assessment should focus on relevant environmental issues relating to the use and disposal of FDA-regulated materials, rather than the production of such materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances that indicate any 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 intended use of the FCS as a colorant for food-contact polymers. In these applications, the FCS is expected to be entirely incorporated into and remain with the finished food-contact article. Any waste material generated in this process, *e.g.*, plant scrap, is expected to be disposed of as part of the food-contact article manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal of the finished food-contact material containing the FCS by the end consumer will be by recycling or conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. Considering the low organic content of the FCS, only very low levels of combustion products are expected when articles containing the FCS are disposed by means of incineration.[1]

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the United States Environmental Protection Agency (EPA) under 40 C.F.R. Part 98.

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[1] The maximum carbon content of the FCS is 0.42%, calculated based on the molecular formula of NOPA, $C_8H_{19}PO_3$ (MW = 194), and the maximum treatment level of 0.85%:
% C = 0.85% NOPA × (8 × 12) ÷ 194 = 0.42%.

Based on the confidential market volume and the estimated portion of municipal solid waste (MSW) that is combusted [2], the expected carbon dioxide equivalent (CO_2-e) emissions (identified in the confidential attachment to the Environmental Assessment) are far below 25,000 metric tons (MT) on an annual basis. To evaluate the significance of these emissions, we have considered whether 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 MT of CO_2-e per year or more to report their GHG emissions to EPA. MSW combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). Thus, GHG emissions resulting from the use and disposal of the FCS as it relates to the incineration of articles containing the FCS in MSW combustion facilities will be managed under these regulations. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated. Further, as the FCS contains elements that are commonly found in MSW (e.g., carbon, hydrogen and oxygen), the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (i.e., 40 C.F.R. Part 60 and/or relevant state and local laws).

To access land disposal impacts, we compared the confidential market volume information for the FCS (contained in a confidential attachment to the EA), to the annual MSW generation (292 million tons), and to the portion of that total that is landfilled (146 million tons) 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. Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of landfill disposal of food-contact articles comprised of the FCS, in light of EPA's regulations governing municipal solid waste landfills. (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

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., as the FCS is a solid, primarily inorganic particle, that does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

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[2] According to the United States Environmental Protection Agency's 2018 update regarding municipal solid waste (MSW) in the United States, of the 292.4 million tons of MSW generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, 32.1% was recovered (a combination of waste recovered from recycling and for composting), and 6.1% was processed through other food management pathways. *See* United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Tables and Figures (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

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. 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. Similarly, no significant effects on the concentrations of and exposures to any substance in terrestrial ecosystems are anticipated as a result 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 FCS in the manufacture of food-contact materials and articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. 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 polymer is not expected to threaten a violation of applicable laws and regulation, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW 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 or resources since the FCS will replace the use of other food-contact materials. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products already being marketed, including NOPA-modified TiO2 that is the subject of effective FCNs 38, 419, and 2279, for which the FCS will serve as a substitute. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

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, the use of the FCS as proposed is not reasonably expected to result in any significant environmental impacts that require mitigation procedures.

11. Alternatives to the Proposed Action

No 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 environmental impact.

12. List of Preparers

Cynthia B. Lieberman, J.D., Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Many years of experience in preparing environmental assessments for FCNs.

Jade C. Williams, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Experienced in preparing environmental assessments for FCNs.

13. Certification

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

Signature: 

Cynthia B. Lieberman, Partner
Counsel for Kronos (US), Inc.
Date: April 18, 2025

14. References

1. United States Food and Drug Administration, *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*, Appendix V, Table 2, *available at*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry.

2. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures*, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

15. Appendices

1. Confidential Addendum to Environmental Assessment