Environmental Assessment

1.	**Date:**	February 24, 2023
2.	**Name of Applicant/Petitioner:**	Tronox Holdings plc
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

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS) identified as "Bis(2,4,4-trimethylpentyl)phosphinic acid-modified titanium dioxide (produced by chemically reacting bis(2,4,4-trimethylpentyl)phosphinic acid ("bis") with titanium dioxide to achieve a treatment level of 0.6% bis by weight of the pigment)" when used in food-contact applications.

The FCS is the reaction product of Bis(2,4,4-trimethylpentyl)phosphinic acid ("Bis") with titanium dioxide (TiO_2). The Bis treatment level is up to 0.6% Bis by weight of pigment. Pigments that have been surface-treated with Bis will be used as colorants for polymers, at up to 20% by weight of polymers, in contact with 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").[1] The FCS is not intended for use in contact with infant formula and human milk, as such uses were not included as part of the intended use of the substance in the FCN. The Bis surface treatment interacts with the titanium dioxide pigment to prevent particle agglomeration and improve dispersibility in polymer matrices. The intended use of the Bis is analogous to the intended use and technical function of dispersants regulated under 21 C.F.R. § 178.3725 ("Pigment dispersants"). The finished pigment is used as colorants for polymers, analogous to the function of colorants for polymers regulated under 21 C.F.R. § 178.3297 ("Colorants for polymers").

The Notifier does not intend to 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

[1] Food and Drug Administration, "Food Types & Conditions of Use for Food Contact Substances," *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

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 (MSW) generally.[2] According to the Environmental Protection Agency (EPA), it is estimated that, as of 2020, of the 292.36 million tons of MSW generated, approximately 50.0% of MSW is 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.[3] As the FCS is expected to be 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.[4]

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

The FCS that is the subject of this notification is "Bis(2,4,4-trimethylpentyl)phosphinic acid-modified titanium dioxide (produced by chemically reacting bis(2,4,4-trimethylpentyl)phosphinic acid ("bis") with titanium dioxide to achieve a treatment level of 0.6% bis by weight of the pigment). The CAS Registry Number, molecular formula, and molecular weight of the Bis surface treatment are 83411-71-6, $C_{16}H_{35}O_2P$, and 290.4 g/mol, respectively. Titanium dioxide (CAS Reg. No. 13463-67-7) is chemically identified as TiO_2. The Bis treatment level is up to 0.6% Bis by weight of pigment. The Bis surface treatment attached to the surface of the TiO_2 pigment through the hydroxyl moiety of the compound. The an example chemical structure of the FCS pigment surface is shown below.

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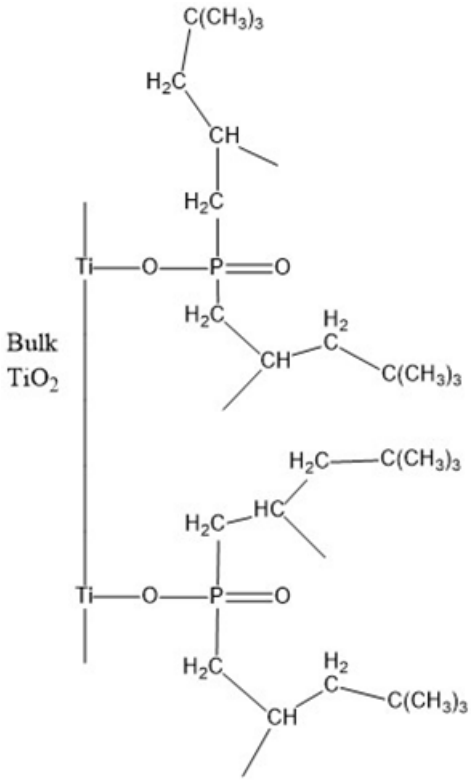
[2] Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), *available at*: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] *Id.*

[4] By assuming that none of the FCS is recycled, 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% will be land-disposed.



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an environmental assessment (EA) ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production of, FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances[5] in this case indicative of any significant adverse environmental impact as a result of 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 materials containing the FCS. In these applications, the FCS is expected to be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are

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[5] Such extraordinary circumstances would include: (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 to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other federal law.

expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.[6] We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling.

The FCS is composed of the elements titanium, carbon, hydrogen, oxygen, and phosphorous. Thus, when properly incinerated, the combustion products of the FCS may include titanium dioxide, carbon dioxide and water.[7] The carbon content of the organic portion of the FCS (66.2% C) 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) and is below 25,000 metric tons carbon dioxide equivalent (CO2-e) emission per MSW combustor (MSWC) on an annual basis.[8] Thus, the concentrations of carbon dioxide in the environment will not be significantly altered by the proper incineration of the polymers in which the FCS is used, in the amounts utilized for food packaging applications, as the host polymers will be incinerated whether or not they contain the FCS.

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 C.F.R. Part 60 and/or relevant state and local laws). In this context, the EPA, under 40 C.F.R. § 98.1, "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 C.F.R. § 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 C.F.R. § 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.

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[6] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

[7] When burned, the phosphorous content of Bis is expected to be retained on the titanium dioxide pigment surface as phosphates or pyrophosphates, as inert solids.

[8] *See* Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

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 articles, 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 C.F.R. 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 food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill. The lack of any significant leaching is further supported by the inherent physical properties of the FCS pigment. The FCS is not expected to migrate out of the polymers in which it is employed due to its inherent properties of being an insoluble, inorganic, and macroscopic pigment. The low loading of organic surface treatment (0.6%) onto the TiO_2 surface provides utility in processing with polymers, but it does not alter the non-migratory nature of the pigment.

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. The analysis discussed above in Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

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. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS. This is supported by the results of extraction studies submitted as a confidential attachment to the environmental assessment. As described therein, extractions were performed using low-density polyethylene (LDPE) plaques that contained 20% of a 0.32% bis-modified titanium dioxide by weight of LDPE with 4% acetic acid and 10% ethanol for 10 days at 60°C. Based on extracted phosphorous content, adjusted for background phosphorous in the blank simulants, Bis was estimated in the extracts at 42 parts per billion (ppb) and 155 ppb in 4% acetic acid and 10% ethanol, respectively. These conditions and solvents greatly exaggerate actual environmental exposure conditions. Therefore, the quantity of bis-modified titanium dioxide extractives, under the less severe conditions typical of solids waste deposited in landfills will be minimal and not leach into water at concentrations that will threaten any fresh water,

estuarine, or marine ecosystems.[9] Furthermore, the low production and use level of bis surface treatment in the FCS for food-contact applications precludes any significant, concentrated environmental releases. Thus, 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 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

The only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of small quantities of combustion products and leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

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 as a modified titanium dioxide colorant for food-contact polymers 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 (*e.g.*, pigment dispersants regulated under 21 C.F.R. § 178.3725 ("Pigment

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[9] The extraction level into 10% ethanol under exaggerated environmental release conditions (0.155 ppm) is below the most sensitive aquatic toxicity endpoint identified for the Bis surface treatment, an EC_{50} > 9.9 mg/L in *Daphnia magna*. Any potential extractives due to the use of the FCS will be significantly diluted in water waste systems. *See* https://echa.europa.eu/da/registration-dossier/-/registered-dossier/11706/6/2/4. *See also* https://echa.europa.eu/da/registration-dossier/-/registered-dossier/11706/6/2/4/?documentUUID=bfe4f802-1839-4cac-8239-3163c6f18e75.

dispersants") and colorants for polymers regulated under 21 C.F.R. § 178.3725 ("Colorants for polymers").

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this notification becoming effective.

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 using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive regulated polymer colorants). Thus, no significant adverse impacts were identified that require mitigation measures.

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, N.W., Suite 500 West, Washington, D.C. 20001. Ms. Lieberman has over 14 years of experience counseling and representing corporate entities on Food Contact Notifications, including their Environmental Assessments.

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 over six years of experience drafting FCN submissions and EAs.

13. Certification

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

Date: February 24, 2023

Signature: 

14. References

1. Food and Drug Administration, "Food Types & Conditions of Use for Food Contact Substances," *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), *available at*: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

3. ASTM, Standard Practice for Coding Plastics Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

4. Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

5. European Chemicals Agency Registration for Bis(2,4,4-trimethylpentyl)phosphinic acid. *See* https://echa.europa.eu/da/registration-dossier/-/registered-dossier/11706/6/2/4. *See also* https://echa.europa.eu/da/registration-dossier/-/registered-dossier/11706/6/2/4/?documentUUID=bfe4f802-1839-4cac-8239-3163c6f18e75.

15. Appendices

1. Confidential Environmental Assessment
2. Confidential Extraction Test Report