

Environmental Assessment

1. **Date:** June 20, 2024
2. **Name of Applicant/Notifier:** Rianlon 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

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), phosphorous acid, cyclic neopentetetrayl bis(2,4-di-*tert*-butylphenyl) ester (CAS Reg. No. 26741-53-7), when used in food-contact materials. The FCS is intended for use as an antioxidant at levels up to 750 parts per million (ppm) by weight in polypropylene homopolymers and copolymers authorized for use in contact with all food types under Condition of Use A (“High temperature heat-sterilized (e.g., over 212°F)”)¹. The FCS may be used in conjunction with triisopropanolamine (TIPA; CAS Reg. No. 122-20-3) at a maximum use level of 1 percent by weight of the FCS.

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

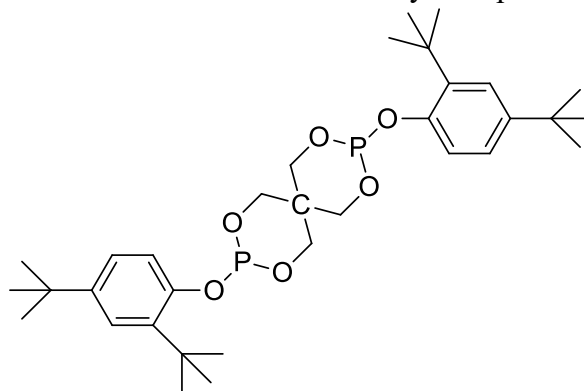
Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste is currently

¹ See United States 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>.

deposited in land disposal sites, 11.8% is combusted, and 32.1% is recovered (a combination of waste recovered for recycling and for composting) and 6.1% was processed through other food management pathways.² The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

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

The subject of this notification is phosphorous acid, cyclic neopentetetrayl bis(2,4-di-*tert*-butylphenyl) ester (CAS Reg. No. 26741-53-7). The FCS has a molecular formula of $C_{33}H_{50}O_6P_2$ (605 g/mol). The structure of this substances may be represented as follows:



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental Assessments”), 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 not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS will be entirely incorporated into finished articles, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste material generated during the manufacture of the finished articles, *e.g.*, plant scraps, is expected to be disposed as part of the finished article manufacturer’s overall nonhazardous solid waste in accordance with established procedures.

² See *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/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

The FCS consists of carbon, hydrogen, oxygen, and phosphorous. Triisopropanolamine, which may be used in conjunction with the FCS, consists of carbon, hydrogen, oxygen, and nitrogen. When properly incinerated, the combustion products resulting from this mixture are expected to be carbon dioxide, nitrous oxide, and water. The carbon and nitrogen content of the FCS/triisopropanolamine mixture has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (provided in a 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.³

Thus, the concentration of carbon dioxide equivalents in the environment will not be significantly altered by the proper incineration of the polymers containing the FCS in the amounts utilized for food contact 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 C.F.R. Part 60, 40 C.F.R. Part 98.2, and/or relevant state and local laws). In this context, the United States EPA, under 40 C.F.R. Part 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 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 adverse environmental impacts are anticipated resulting from combustion of the FCS, with or without added triisopropanolamine, 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 C.F.R. Part 258).” These requirements are enforced by state solid-waste and management programs. Therefore, based on the 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 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 does not readily

³ U.S. estimated 75 MSWCs. 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>.

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. 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 as detailed in Section 6 of this EA.

B. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS. The fate of 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 concentration 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 are expected to result in virtually no leaching of FCS components under normal environmental conditions when the food-contact articles in which they are contained are disposed of. Furthermore, the very 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 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, 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 polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the 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 involves the use of natural resources such as petroleum products, coal, and the like. The manufacturer of the FCS will consume comparable amounts of energy and resources as similar products already being marketed (*i.e.*, antioxidants permitted for use in PP 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.

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 articles fabricated with the subject FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of material that the subject FCS would replace. Such action would have no anticipated environmental impact.

12. List of Preparers

Mark Thompson, JD, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001. Mr. Thompson has over 15 years of experience with Environmental Assessments for FDA submissions.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Dr. Coneski has over 10 years of experience performing evaluations relating to all aspects of preparing FCNs, 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: June 20, 2024



Mark Thompson
Counsel for Notifier

14. References

1. 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.

15. Attachment

1. Attachment 13 – Confidential Environmental Information