Environmental Assessment

1. Date: January 26, 2026

2. Name of Applicant/Petitioner: SI Group

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 the Proposed Action

The action requested in this Notification is to authorize the use of cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6) as a food-contact substance (FCS). The FCS is intended for use as an antioxidant and/or stabilizer in polyethylene terephthalate (PET) polymers at levels not exceeding 0.2 percent by weight of finished PET polymer, which may contact all types of food 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 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 FCS may be used in conjunction with triisopropanolamine (TIPA; CAS Reg. No. 122-20-3) at levels not exceeding 1 percent by weight of the FCS.

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 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

[1] FDA's food types and conditions of use are defined in 21 C.F.R. § 176.170(c), Tables 1 and 2, respectively. *See also* United States Food and Drug Administration, "Food Types & Conditions of Use for Food Contact Substances," https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

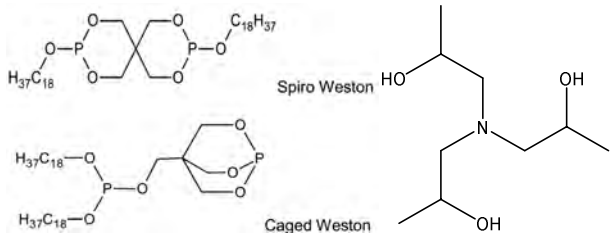
recycled in quantities similar to those reported for municipal solid waste generally.[2] According to the United States Environmental Protection Agency (EPA), it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of MSW was land-disposed; 23.6% was recycled; 11.8% was combusted; 8.5% was composted and 6.1% was handled through other food management pathways.[3]

With regard to PET bottles specifically, the National Association for PET Container Resources (NAPCOR) estimates that 28% of PET bottles were recycled in 2019.[4] It is anticipated that the PET manufactured containing the FCS would be marked with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made and thus coded for identification as PET.[5] Using this recycling rate for PET bottles, specifically, it is calculated that 13.1% of food-contact materials containing the FCS will be combusted annually (11.8% combusted ÷ (11.8% combusted + 28% recycled + 50% land disposed) = 13.1% combusted. 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

The FCS that is the subject of this Notification is cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6). The molecular formula for the FCS is $C_{41}H_{82}O_6P_2$ and consists of two structural isomers. Triisopropanolamine (CAS Reg. No. 122-20-3), which may be used in conjunction with the FCS at a maximum level of percent by weight of the FCS, has a molecular formula of $C_9H_{21}NO_3$.

The structure of the FCS, including triisopropanolamine, may be represented as follows:



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

[3] *See id.*

[4] *See* National Association for PET Container Resources (NAPCOR), NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow, https://napcor.com/news/4970-2.

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

The FCS is intended for use as an antioxidant and/or stabilizer polymeric food-contact materials by inhibiting oxidation, and thus the deterioration of the technical performance of polymers used in food-contact materials.

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 food-contact materials. The Notifier is not aware of any information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from manufacture of the FCS. Such extraordinary circumstances would include: (a) 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; (b) the proposed action threatening a violation of federal, state, or local environmental laws or requirements; or (c) 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 and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other federal law. 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 in food-contact materials. The FCS will be entirely incorporated into finished food-contact articles and is expected to remain with these materials throughout the use of the FCS in food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS for food-contact use in the United States is provided in the confidential appendix to this Environmental Assessment.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact articles containing 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.

The subject FCS consists of carbon, hydrogen, phosphorus and oxygen. TIPA, which may be used in conjunction with the FCS, consists of carbon, hydrogen, oxygen and nitrogen. When properly incinerated, the combustion products resulting from the FCS/TIPA mixture are expected to be carbon dioxide, nitrous oxide, and water. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide equivalent emissions from the FCS has been calculated in a confidential appendix to this Environmental Assessment, as well as an assessment of the worst-case release.

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which 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 metric tons (MT) of carbon dioxide equivalents (CO_2-e) or more per year to report their greenhouse gas (GHG) emissions to the EPA. 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.

Based on the anticipated market volume for the FCS, the expected carbon dioxide equivalent emissions, as detailed in the confidential appendix to this Environmental Assessment, are below 25,000 MT on an annual basis. Because the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental 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 (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

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 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 of the substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant 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 articles manufactured with this FCS.

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 subject 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.

C. Land

Due to 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 are 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 low production volume anticipated for the FCS in food-contact applications precludes any substantial release to the environment of its components. Thus, we have 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 subject FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject FCS in landfills and by combustion are not anticipated as only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of food-contact articles containing the subject FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *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 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 PET 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.

For the foregoing reasons, no 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 from the FCS. Thus, the use of

the FCS as proposed is not reasonably expected to result in any new environmental problem requirement mitigation measures of any kind.

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 anticipated environmental impact.

12. List of Preparers

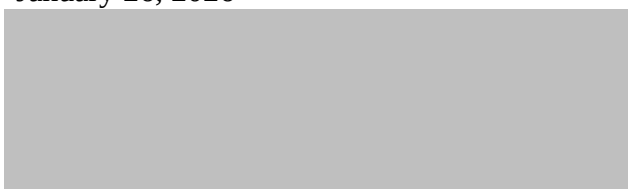
Kathryn C. Skaggs, J.D., MPH, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Ms. Skaggs has over 15 years of experience drafting FCN submissions and environmental assessments.

Jason Schmidt, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Dr. Schmidt has over 15 years of experience drafting FCN submissions and 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: January 26, 2026

Signature: 

Kathryn C. Skaggs
Counsel for Notifier

14. References

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

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

3. National Association for PET Container Resources (NAPCOR), NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow, https://napcor.com/news/4970-2.

4. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, D7611/D7611M-20 (2020).

15. Appendices

1. Confidential Appendix to Environmental Assessment