Environmental Assessment

1. Date: November 2, 2023

2. Name of Applicant/Petitioner: SI Group

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

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4. Description of Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (CAS Registry Number 939402-02-5), when used in food-contact materials. The FCS is intended for use as an antioxidant at levels up to 0.2 percent by weight in polyethylene terephthalate polymers authorized for use in contact with all food types[1] under 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").[2] The FCS will be used in conjunction with triisopropanolamine (TIPA; CAS Reg. No. 122-20-3) at a maximum use level of 0.75 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.

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[1] The conversion of 0.2% to parts per million is shown as follows: 0.2% x (1,000,000 parts per million/100%) = 2,000 parts per million

[2] FDA's food types and Conditions of Use are defined in Tables 1 and 2 at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

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 U.S. Environmental Protection Agency (EPA) data for 2018, published in 2020, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting) and 6.1% was processed 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 the 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 Subject of the Proposed Action

The subject of this notification is phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (CAS Registry Number 939402-02-5). The various esters present in the FCS mixture have molecular formulas of $C_{33}H_{45}O_3P$ (520 g/mol), $C_{38}H_{55}O_3P$ (590 g/mol), $C_{43}H_{65}O_3P$ (660 g/mol), and $C_{48}H_{75}O_3P$ (730 g/mol). Triisopropanolamine, which may be used in conjunction with the FCS at a maximum level of 0.75 percent by weight of the FCS, has a molecular formula of $C_9H_{21}NO_3$ (191.27 g/mol). The structure of the individual components of this mixture, including triisopropanolamine, may be represented as follows:

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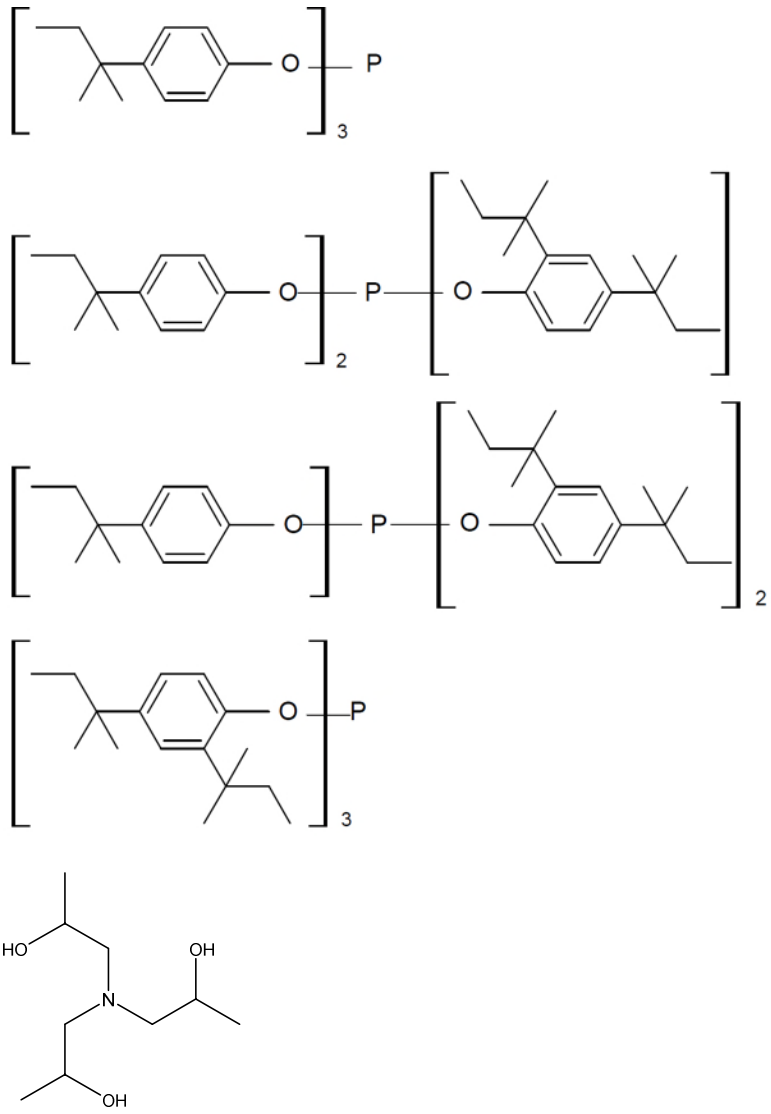
[3] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[4] *See* National Association for PET Container Resources (NAPCOR), NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow, *available at:* https://napcor.com/news/4970-2/ (last accessed April 1, 2023).

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



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 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.

The FCS consists of carbon, hydrogen, phosphorus, and oxygen. Triispropanolamine, 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/triispropanolamine 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 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.[6]

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 packaging 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. 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 CFR 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 CFR 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, without 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 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.

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[6] U.S. estimated 75 MSWCs. See US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

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 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 is 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 Environmental Protection Agency'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 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 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 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.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated within 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 the materials that the subject FCS would replace. Such action would have no anticipated environmental impact.

12. List of Preparers

1. 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 30 years of experience drafting Food Additive Petitions, FCN submissions, and Environmental Assessments.

2. Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Coneski has 10 years of experience preparing FCN submissions, including their Environmental Assessments.

13. Certification

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

Date: November 2, 2023

George G. Misko

Counsel for SI Group

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

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 Resource Conservation and Recovery, December 2020, *available at*: https://www.epa.gov/sites/production/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, *available at:* https://napcor.com/news/4970-2/ (last accessed July 30, 2023).

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

15. Attachments

1. Confidential Attachment to Environmental Assessment.