Environmental Assessment

1. Date	February 2, 2026
2. Name of applicant/notifier	Jiangsu Evergreen New Material Technology Incorporated Company
3. Address	All communications on this matter are to be sent in care of Consultant for Notifier: Maxwell Song, Regulatory Affairs Specialist. REACH24H Consulting Group, 10th Floor, C1 building, No. 76 North Longzhou Road, Yuhang District, Hangzhou, Zhejiang, China, 311121 E-mail: Songmingzhang@reach24h.com

4. Description of proposed action

a) Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance, triisotridecyl phosphite (CAS Reg. No. 77745-66-5), when used as an antioxidant, in the manufacture of PVC and LLDPE. The FCS may be used at levels not to exceed 1 wt% of the finished PVC in contact with all food types under conditions of use (COU) B through H and at levels not to exceed 0.25 wt% of LLDPE complying with 21 CFR 177.1520(c), items 3.1 and 3.2, where the density of the polymer is not greater than 0.94 g/cm^3. LLDPE containing the FCS may be used in contact with dry (containing no free fat or oil), aqueous, acidic, and alcoholic foods (up to 15 % alcohol) under COU B through H. The FCS may contain no more than 1 wt% of triisopropanolamine (TIPA, CAS No. 122-20-3) to stabilize the FCS. The FCS is not for use in contact with infant formula and breast milk. Such uses were not included as part of the intended use of the substance in the FCN.

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) 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. Finished 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.

According to the U.S. Environmental Protection Agency's (EPA) 2018 update regarding municipal solid waste in the United States, which is the most recent data available, approximately 50.0% of municipal solid waste (MSW) is currently 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[1]. As the FCS is expected to be primarily

[1] Table 35 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material 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/default/files/2020-11/documents/2018_ff_fact_sheet.pdf

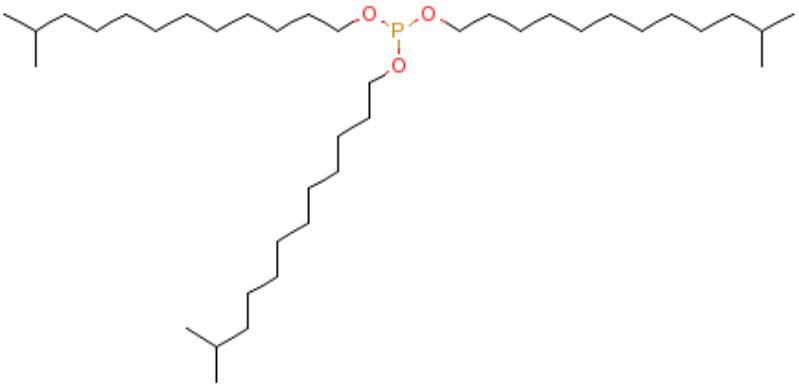
disposed of through combustion or land-filling, to evaluate the most conservative environmental introduction of the FCS, we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually[2]. 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 substance that is the subject of the proposed action

The FCS that is the subject of this Notification is triisotridecyl phosphite. Chemical information on this substance is presented below:

CAS Reg. No.: 77745-66-5

Structural Formula:



6. Introduction of substances into environment

a) As a Result of Manufacture

Under 21 CFR 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 articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances[3] in this case indicative of any 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.

b) As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration.

[2] This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

[3] 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

Air (Combustion):

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the food-contact substance. The FCS is a high molecular weight polymer and does not readily volatilize and will be cured within a food contact materials or articles. 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 is composed of carbon, hydrogen, oxygen and phosphorus. Based on the elemental composition of the FCS, a greenhouse gas GHG analysis was performed. This analysis is based upon the elemental composition of the FCS and assumes that 19.1% (described under 4(c)) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO_2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis, the expected CO_2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

To evaluate the significance of the environmental impact of these GHG emissions, we consider whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment. As noted above, GHG emissions from MSW combustion facilities are regulated under 40 CFR § 98.2. The expected carbon dioxide equivalent emissions, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities. As the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (i.e., 40 CFR 60), no significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS.

Landfill:

Only extremely low levels, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA's regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste 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, and to have ground-water monitoring systems (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.

Considering the factors discussed above, 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.

Water:

No significant effect on the concentrations of and exposure 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 due to EPA's regulation at governing landfills (40 CFR part 258).

Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact on the aqueous environment resulting from post-consumer disposal of food-contact articles that contain the FCS due to

the proposed use.

7. Fate of emitted substances in the environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments. Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental effects of released substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released into the environment during use and disposal of food-contact articles containing the FCS.

Based on these considerations, no adverse effect on organisms in the environment or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of resources and energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. Therefore, there will be no anticipated impact on current or future recycling programs.

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative FCS.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to 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 which the FCS would otherwise replace; such action would have no anticipated environmental impact.

12. List of preparers

Maxwell Song, Regulatory Affairs Specialist, 5 years of experience related to the preparation of Food Contact Notifications and food packaging compliance matters under

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13. Certification

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

14. Attachment

Confidential Attachment to the Environmental Assessment (Attachment 14 in this Notification)

Date: February 2, 2026



Maxwell Song, Regulatory Affairs Specialist

Consultant for Jiangsu Evergreen New Material Technology Incorporated Company