Environmental Assessment

1.	**Date**	July 15, 2020
2.	**Name of Applicant/Notifier**	BASF Corporation
3.	**Address**	BASF Corporation 500 White Plains Road Tarrytown, NY 10591-9005 Telephone: (914) 785-2122

4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of tris (2,4-di-tert-butylphenyl) phosphite (CAS Reg. No. 31570-04-4) for use as an antioxidant and/or stabilizer in styrene block co-polymers complying with 21 CFR 177.1810; intended for single and repeat food contact use. Use of this FCS is needed to increase thermal stability of styrene block co-polymers.

1. The FCS may be used at levels not to exceed 0.4 percent by weight in finished food-contact articles in contact with all food types under Conditions of Use A through H identified and described in Tables 1 and 2, respectively, of 21 CFR 176.170(c).

The FCS is not for use in contact with infant formula and human milk, as these uses were not specifically addressed in the FCN.

The Notifier does not intend to produce finished food-contact articles, as the FCS is an additive that is used in the manufacture of articles for food-contact applications. The FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with 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 resins containing the FCS will occur nationwide. It is estimated that, of the 14,490,000 tons of plastic containers and packaging present in municipal solid waste (MSW) generated in 2017, approximately 69.9% generally was land disposed, 17.1% was combusted, and 13.0% was recovered for recycling.[1]

[1] United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2017 Fact Sheet, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, November 2019. Available at the following website: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

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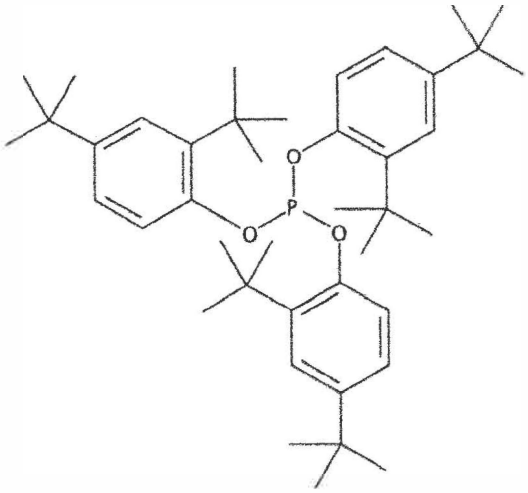
5. Identification of Substance that Is the Subject of the Proposed Action

Chemical Name: Tri (2,4-di-*tert*-butylphenyl) phosphite

CAS Registry Number: 31570-04-4

Chemical Formula: C42H63O3P

Chemical Structure:



6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

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 articles. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action 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.

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b. Use in Polymer Manufacture

No significant environmental release is expected upon the use of the subject FCS to fabricate food-contact articles. In these applications, the FCS (*i.e.*, an additive for polymers) is expected to be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

c. Introduction of Substances into the Environment as a Result of Use/Disposal

Air: (Combustion)

The subject FCS consists of the elements carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment and an assessment of these worst-case releases is also included in the same confidential appendix. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide and assumed that 17.1% of the market volume will be combusted.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting. To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on confidential market volume data, the expected carbon dioxide equivalent (CO_2-e) 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 combustion of the FCS in MSW combustion facilities.

Soil and Water: (Landfill)

Only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have

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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. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. Even if a very small amount of substances leach from the landfilled food-contact material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

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

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

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 in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS is intended to be used in food-contact resins in place of similar, phenol-free hydroxylamine-based, stabilizers now on the market for use in food-contact applications.

The replacement of other antioxidants and/or stabilizers by the subject FCS in food-contact resins is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of the stabilizer. Food contact materials produced from resins containing the FCS are expected to be disposed of in the same pattern as currently seen for styrene block polymers and include recycling. These polymers already contain antioxidant materials, including the FCS (i.e., FCNs 1463, 1237, 1230, 829, 814), and this notified use would be substitutional to these other authorized uses. Therefore, significant impacts to recycling are not anticipated.

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10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to resulto from the use and disposal of food-contact materials fabricated from the use of the FCS. 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 the Proposed Action

No potential adverse environmental effects are identified herein which would necessitateo alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the currently marked materials; such action would have no significant environmental impact.

12. List of Preparers

John C. Hand, Ph.D in Biochemistry, 1 year experience related to the preparation of Food Contact Notifications, 14 years' experience generating data for Food Contact Notifications and 18 years working in FDA regulated industries.
Product Regulation Specialist, Senior, BASF Corporation 500 White Plains Road, Tarrytown, NY 10591.

13. Certification

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

[redacted]

John C. Hand
Date: July 15, 2020

14. List of References

United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2017 Fact Sheet, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, November 2019. Available at the following website: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

15. List of Attachments

1.o Confidential Environmental Assessment.o