ENVIRONMENTAL ASSESSMENT
FOOD CONTACT NOTIFICATION
Dover Chemical Corporation

1.	**Date:**	July 1, 2019
2.	**Name of Applicant/Notifier:**	Dover Chemical Corporation
3.	**Address:**	3676 Davis Road, NW Dover, Ohio 44622 All communications on this matter are to be sent in care of Counsel for Notifier: Devon Wm. Hill, Partner Keller and Heckman LLP 1001 G Street, N.W., Suite 500 West Washington, D.C. 20001 Telephone: (202) 434-4279 Facsimile: (202) 434-4646 E-mail: hill@khlaw.com

4. Description of the Proposed Action

The action identified in this food-contact notification (FCN) is to provide for the use of the food-contact substance (FCS), triphenyl phosphite, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C_{10-16} alkyl esters (CAS Reg. No. 1821217-71-3) when used at levels up to 0.20% in linear low density polyethylene (LLDPE) films and articles in contact with all types of food 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"). This FCN also covers the use of the food-contact substance (FCS) at a maximum level of 1% in adhesives and pressure-sensitive adhesives, can-end cements, and repeated-use food contact materials. The FCS is also intended to be used in conjunction with triisopropanolamine (TIPA; CAS Reg. No. 122-20-3) at a maximum use level of 2.0% by weight of the FCS when the FCS is used in LLDPE films and articles, adhesives and pressure-sensitive adhesives, can-end cements, and repeated-use food-contact materials. The FCS is not for use in contact with infant formula and breast milk because such uses were not included as part of the intended use of the substance in the FCN.

The FCS is meant to act as a thermal stabilizer for the resins to which it is added. The Notifier does not intend to produce finished food packaging, as the FCS is an additive that is used in the manufacture of resins used for food-contact applications. Resins containing the FCS will then be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with resins 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 resins containing the FCS will occur nationwide. It is estimated that, of the 14,680,000 tons of plastic containers and packaging present in municipal solid waste (MSW) generated in 2015, approximately 68.6% generally was land disposed, 16.8% was combusted, and 14.6% was recovered for recycling.[1]

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

The FCS that is the subject of this notification is triphenyl phosphite, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, $C_{10\text{-}16}$ alkyl esters (CAS Reg. No. 1821217-71-3). The product is marketed under the trade name LGP-12.

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 articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances 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.

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

No environmental release is expected upon the use of the subject FCS to fabricate packaging materials. 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.

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[1] United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, July 2018 (Page 9, Table 8). Available at the following website: https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

The subject FCS consists of the elements carbon, hydrogen, oxygen, and phosphorus. 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.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. 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 equivalents (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 in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Moreover, 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 the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential appendix to the EA, 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.

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 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 composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems.[2] 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 packaging 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

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject FCS as a result of the use of the FCS as a thermal stabilizer. The FCS is a polymeric material and does not readily volatilize during use of the FCS, and the analysis discussed above in Item number 6 demonstrates that no

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[2] 40 C.F.R. Part 258.

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.

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.

Considering 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. Furthermore, the use of the FCS as a thermal stabilizer is a replacement for other phosphite stabilizers already on the market for use in food-contact applications and precludes any substantial increase in release to the environment of its components; examples of other phosphite stabilizers already permitted for use in the same polymers proposed in this Notification are those cleared by 21 C.F.R. § 178.2010 ("Antioxidants and/or stabilizers for polymers") and FCN Nos. 20, 21, 22, 232, 337, 626, 861, 895, 960, 1230, 1282, 1545, 1724, and 1769. 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 subject FCS in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, 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 the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *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-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 phosphite thermal stabilizers now on the market for use in food-contact applications.

The replacement of other thermal 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 thermal stabilizers. Packaging materials produced from resins containing the FCS are expected to be disposed of according to the same patterns when they it is used in place of current materials. Thus, there will be no impact on current or future recycling programs.

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 resins containing 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 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 environmental impact.

12. List of Preparers

Kristin P. Wiglesworth, Ph.D. in Chemistry, 2 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 13 years of total experience in FDA regulated industries. Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001.

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications. Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

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

[redacted]

Devon Wm. Hill
Counsel for Dover Chemical Corporation
Date: July 1, 2019

14. References

1. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovert and Landfilling in the United States*, July 2018 (Page 9, Table 8). *See*

https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

2. 40 C.F.R. Part 258.

15. Appendices

1. Confidential Environmental Information (**CONFIDENTIAL**) (Attachment 2).