Environmental Assessment

1. **Date:** November 30, 2024 *

2. **Name of Applicant / Notifier** Chitec Technology Co., Ltd.

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4. **Description of the Proposed Action**

a) Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of [4-tert-butyl-2-(5-tert-butyl-2-oxo-3H-benzofuran-3-yl)phenyl] 3,5-ditertbutyl-4 hydroxy-benzoate (CAS No.: 1261240-30-5). The FCS is intended to be blended with hindered phenolic and phosphite-based antioxidants to provide a synergistic effect. The FCS will be used in polyolefin articles at a level up to 1) 500 ppm in polyolefin articles in contact with aqueous and acidic foods under Conditions of Use (COU) A through H; and 2) 100 ppm in polypropylene articles (thickness shall not exceed 10 mil) in contact with dry, alcoholic and fatty foods under COU A through H as describe in Tables 1 and 2 of 21 CFR 176.170(c).[1] 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 meant to act as a multi-functional, benzofuranone-based antioxidant for the resin to which it is added. It exhibits high synergistic effect in both MFA stabilization and color protection. It stabilizes the melt flow index and significantly reduces yellowing.

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. Food contact articles produced with the FCS in the U.S. 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 will occur nationwide.

According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted,

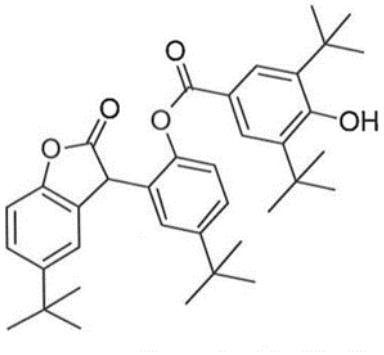
[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature to remove outdated or extraneous language and to format the text for conformance with Section 508 assistive technologies.

23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[2] As the FCS is expected to be primarily disposed of through combustion or land-filling (i.e., not recycled, composted, or handled through other food management pathways), 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.[3]

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

The FCS that is the subject of this Notification is [4-tert-butyl-2-(5-tert-butyl-2- oxo-3H-benzofuran-3-yl)phenyl] 3,5-ditert-butyl-4-hydroxy-benzoate. Chemical information on this substance is presented below:

CAS Reg. No.:	1261240-30-5
Chemical Formula:	$C_{37}H_{46}O_5$
Structural Formula:	
Appearance:	White crystalline powder
Melting Point:	≥ 183 °C

6. Introduction of Substances into the Environment

a) 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. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances[4] in this case indicative of any adverse environmental impact as a result

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[2] 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/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

[3] 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.

[4] 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 determined under the Endangered Species Act or the

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 (e.g., plant scraps) 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. For food-contact materials 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.

Air (Combustion)

The FCS consists of carbon, hydrogen, and oxygen. These are elements that are commonly found in municipal solid waste. Considering the proposed use and use level of the FCS described under 4(a)., it can be concluded that the FCS will make up an insignificant portion of the plastic containers and packaging presented in the total municipal solid waste (MSW) currently combusted.[5] The products of complete combustion of the FCS are CO2, and water, materials commonly generated in these facilities. Because the release of CO2, a greenhouse gas (GHG) analysis was performed. This analysis is presented in the confidential attachment to the EA and 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 (CO2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis (contained in the confidential attachment to the EA), the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

As such, 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, 40 CFR 98). Thus, no significant environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

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

Convention on International Trade in Endangered Species of Wild Fauna to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

[5] The comparison is contained in the confidential attachment to the EA.

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 substances 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. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS.

Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS,[6] to the annual municipal solid waste (292,360 thousand tons in 2018 from EPA) and concluded that the FCS and the food-contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste in the MSW. 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 to 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.

[6] *Ibid.*

9. Uses 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 other similar antioxidants. Furthermore, packaging materials produced from resins containing the FCS are expected to be disposed of in the same manner when used in place of current materials.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

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

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13. Certification

Date: November 30, 2024

Yini Jin, Regulatory Analyst

Consultant for Chitec Technology Co., Ltd.