Environmental Assessment

1. Date: November 14, 2025

2. Name of Applicant/Notifier: Zhuhai Kingfa Biomaterial Co., Ltd.

3. Address:

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4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), poly(butylene succinate) optionally reacted with glycerol (CAS Reg. No. 56-81-5) and/or hexamethylene diisocyanate (CAS Reg. No. 124-09-4). The FCS is intended for use in coatings, films, molded articles, and thermoformed articles that contact all food types, except alcoholic foods, under Conditions of Use B ("Boiling water sterilized") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials. 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. Therefore, it is anticipated that disposal of food contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.[1] According to U.S. Environmental Protection Agency's (EPA) 2020 update regarding municipal solid waste in the United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018,

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[1] *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed July 2023, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

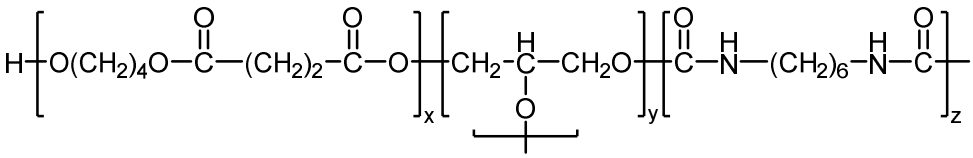
50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[2] As the FCS is expected to be primarily disposed of through combustion, or land-filling (*i.e.*, not composted or handled 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]

Food-contact materials containing the FCS may ultimately be subject to composting because PBS polymers, like the FCS, are compostable. Based on the scarcity of composting facilities nationally, and source controls at the limited existing facilities, the Notifier expects the FCS to be disposed of almost entirely by landfill.[4] Thus, the majority of articles containing the FCS will ultimately be land-disposed or combusted. No significant adverse environmental impact is anticipated due to the landfilling or incinerating of compostable PBS. We did not account for composting in our quantitative CO_2 assessment because the value determined based on incineration provides a worst-case scenario with respect to greenhouse gas emissions. In any event, should some composting of food-contact materials containing the FCS occur, the Notifier does not expect this to adversely impact the environment.

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

Chemical Abstracts Service (CAS) name: poly(butylene succinate) optionally reacted with glycerol (CAS Reg. No. 56-81-5) and/or hexamethylene diisocyanate (CAS Reg. No. 124-09-4)

Structural Formula:



[2] *Id.*

[3] 11.8% Combusted ÷ (11.8 % combusted + 50% land disposed) = 19.1% combusted.

[4] This is further supported by the Environmental Protection Agency's (EPA) *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed July 2023, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf, which confirms that food, yard trimmings, and other municipal solid waste (MSW) organic materials are the categories of waste that are composted in the U.S.; plastics are not included among the materials reported to be composted.

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 materials. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used to fabricate all forms of food-contact articles or films, will be entirely incorporated into the finished food-contact materials, and is expected to remain with the food-contact materials throughout use in food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

The FCS consists of carbon, hydrogen, oxygen, and nitrogen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. The carbon content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the 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.[5] Thus, the concentration of carbon dioxide in the environment will not be significantly altered by the proper incineration of the polymers 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 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 CFR 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 environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

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[5] 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.

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 CFR 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.

7. Fate of Emitted Substances in the Environment

A. Air

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. Because the FCS is a high molecular weight polymer, the FCS does not readily volatize. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from solid waste combustion facilities operating under 40 C.F.R. Part 60.

As indicated above in Item 6, the FCS will replace a portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

B. Water

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 FCS. The fate of finished food-contact materials manufactured with the FCS in 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 concentrations 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 polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of 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.

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. 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 will used in place of other food packaging materials.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Thus, there will be no impact on current 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 the FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant 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 anticipated environmental impact.

12. List of Preparers

Kathryn Skaggs, JD, MPH (Epidemiology and Biostatistics), Partner, Keller and Heckman LLP 1001 G Street NW, Suite 500W, Washington, DC 20001. Ms. Skaggs has 14 years of experience with Environmental Assessments for FDA submissions.

Adam W. Freeman, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Freeman has over 4 years of experience performing evaluations relating to all aspects of preparing FCNs, and 25 years of total experience in FDA-regulated industries.

13. Certification

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

(b) (4)

Kathryn C. Skaggs
Counsel for Notifier
Date: November 14, 2025

14. References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, Accessed July 2023, https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management.

15. Attachment

1. Confidential Attachment – Attachment 14