# Environmental Assessment

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| **1.** | **Date** | November 24, 2025 |
| **2.** | **Name of applicant/notifier** | Zhejiang Honor Biomaterials Co., Ltd. |
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**4. Description of proposed action**

**a) Requested Action**

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of Polylactide (Polylactic acid; PLA) optionally containing up to 16 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2) which will be used to manufacture food contact articles intended to contact all types of food (except for infant formula and human milk), under Conditions of Use B~H as described in Tables 2 of CFR 176.170 (c).[1]

**b) Need for Action**

The FCS is used as a component of food-contact articles, except for use in contact with infant formula and human milk. The FCS is intended as an environmentally-friendly polymer option, after its intended use, is expected to degrade over time to biomass, carbon dioxide, and water in the presence of microorganisms in an aerobic environment.

**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.

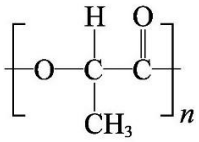
According to the U.S. Environmental Protection Agency's (EPA) report December 2020, it is estimated that, of the 14,530,000 tons of plastic containers and packaging present in municipal solid waste (MSW) generated in 2018, approximately 69.4% generally was land

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

disposed, 16.9% was combusted, and 13.6% was recovered for recycling.[2]
As noted in the same report, food-contact materials manufactured from PLA are not expected to be collected for recycling. Additionally, even though the FCS is compostable, these materials are not likely to be recovered for composting given that commercial composting (i.e., at monitored sites operating at the elevated temperatures, with mixing and aeration, etc.) is not a widely-used disposal option in the United States. Excluding these means of disposal and assuming that all food-contact articles manufactured with the FCS are primarily disposed of by landfill or combustion, we recalculated the disposal pattern based on the quantities of MSW that are landfill or combusted. On this basis, we estimate that approximately 80.4% of the materials will be deposited in landfills and about 19.6% will be incinerated.[3]

## 5. Identification of substance that is the subject of the proposed action

The FCS that is the subject of this Notification is Polylactic acid (9051-89-2). Chemical information on this substance is presented below:

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| Chemical Name | Polylactide (Polylactic acid; PLA) optionally containing up to 16 weight percent D-lactic acid polymer units |
| CAS Reg. No.: | 9051-89-2 |
| Structural Formula: |  |

In the manufacturing process, Lactic Acid and other raw materials were reacted under certain temperature. After the reaction, Polylactic acid (9051-89-2) (FCS) was obtained.

## 6. Introduction of substances into 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 of the manufacture of the FCS. Consequently, information

[2] Table 8 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/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

[3] This amount is calculated as follows: 16.9% combusted / (16.9% combusted + 69.4% landfilled) = 19.6% combusted. The remaining 80.4% will be land disposed (landfilled).

[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 Convention on Intentional 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.

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.

Air (Combustion):

The FCS consists of carbon, hydrogen, 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 $CO_2$, and water, materials commonly generated in these facilities. Because the release of $CO_2$, a greenhouse gas (GHG) is anticipated, a 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 19.6% (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 the estimated GHG emissions are below the threshold for mandatory reporting, 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). 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. As indicated above, the FCS will make up a small portion of the total MSW currently combusted. Thus, no significant adverse environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

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

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.

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 plastic containers and packaging waste (14,530 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 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

[6] The comparison is contained in the confidential attachment.

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 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. For example, the effective FCN 676 already permitted the FCS for the same uses as proposed in this Notification. 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 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 pigments. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for similar pigment products.

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 environmental impact.

## 12. List of preparers

Jenny Zhang, Regulatory analyst, 5 years of experience related to the preparation of Food Contact Notifications and food packaging compliance matters under FDA food contact regulations.
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## 13. Certification

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

## 14. Attachment

Confidential Attachment to the Environmental Assessment (Attachment 15 in this Notification)

Date: November 24, 2025



Jenny Zhang, Regulatory Affairs Specialist

Consultant for Zhejiang Honor Biomaterials Co., Ltd.