Environmental Assessment

1. Date	November 28, 2024*
2. Name of applicant/notifier	Ningbo Tianan Biologic Material Co., Ltd.
3. Address	All communications on this matter are to be sent in care of Consultant for Notifier: Yini Jin, Regulatory Affairs Specialist, REACH24H Consulting Group, 14th Floor, Building No. 3, Haichuang Technology Center, 1288 West Wen Yi Road E-mail: jinyini@reach24h.com

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) Poly-((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyvaleric acid) (CAS Reg. No. 92267-82-8). The FCS is intended for use in single-use food-contact materials and articles under conditions of use B through H as described in Tables 1 and 2 of CFR 176.170 (c).[1] The food-contact articles containing this FCS are intended to come into contact with all food types, except infant formula and human milk.

b) Need for Action

The FCS is a biopolymer and is intended to be used as an alternative to traditional petroleum based polymers that are currently used in the market. The properties of the FCS are expected to be similar to existing polyhydroxyalkanoate polymers (PHA) that are already authorized by FDA for use in food-contact applications (see FCN 1119, 1398, 1835). The FCS is produced by microbial fermentation of glucose and micronutrients.

[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this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature to remove outdated or extraneous language.

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.

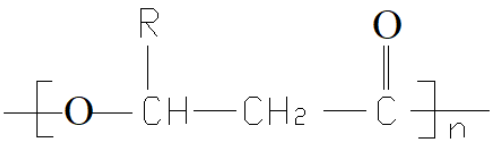
According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[2] As the FCS is expected 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 Poly-((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyvaleric acid). Chemical information on this substance is presented below:

CAS Reg. No: 92267-82-8

Structural Formula:



i. When the R group is –CH3, the monomer is hydroxybutyric acid (HB);

ii. When the R group is –C2H5, the monomer is hydroxyvaleric acid (HV).

[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.

The FCS is manufactured by microbial fermentation of glucose and micronutrients. After fermentation, the FCS is extracted from the cells. The extracted products will be washed and further processed to obtain the final product.

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 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.

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 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.[4] 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

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

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 19.1% (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.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. In particular, 40 CFR § 1508.27(b)(10) states that, when evaluating the 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." As noted above, GHG emissions from MSW combustion facilities are regulated under 40 CFR § 98.2. Based on the confidential market volume information, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment 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 the combustion of the FCS in MSW combustion facilities.

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.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substance 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 due to EPA's regulation at governing landfills (40 CFR part 258).

Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS[5], 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 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.

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

[5] Data provided in a confidential attachment

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 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 substances. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for similar polymer products.

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 significant environmental impact.

12. List of preparers

Yini Jin, Regulatory analyst, REACH24H CONSULTING GROUP, 14th Floor, Building No. 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China 311121

13. Certification

The undersigned official certifies that the information provided herein is true,

accurate, and complete to the best of her knowledge.

Date: November 28, 2024
Yini Jin, Regulatory analyst

Consultant for Ningbo Tianan Biologic Material Co., Ltd.