ENVIRONMENTAL ASSESSMENT

1. Date: December 30, 2022

2. Name of Applicant/Notifier: CJ CheilJedang Corporation

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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), butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid (CAS Reg. No. 125495-90-1), containing from 25 to 35 weight percent 4-hydroxybutanoic acid. The clearance established by this Notification would permit the use of the FCS in blends with polyesters. Specifically, the FCS may be used at up to 20% in contact with all foods, except those containing more than 15% alcohol, under Conditions of Use B through H; the FCS may be used at up to 30% in contact with all foods, except those containing more than 15% alcohol, under Conditions of Use C through G; and the FCS may be used at up to 40% in contact with all foods under Conditions of Use D through G.

The Notifier does not intend to produce finished food packaging from the FCS or mixtures of the FCS with polyester. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact articles. 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 the FCS will occur nationwide, with the material being land disposed, or combusted in quantities similar to those

reported for municipal solid waste generally.[1] According to the U.S. Environmental Protection Agency's (EPA) 2020 update regarding municipal solid waste (MSW) in the United States, it is estimated that, of the 292.36 million tons of MSW generated in 2018, 50.0% of MSW generated 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 food-contact materials containing the FCS are 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 polyhydroxyalkanoate (PHA) polymers, like the FCS, are compostable, as are some of the other biopolyesters that may be blended with the FCS. Nevertheless, based on the scarcity of composting facilities nationally, and source controls at the limited existing facilities, the Notifier expects the food-contact materials containing 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 PHA. We did not account for composting in our quantitative carbon dioxide (CO_2) assessment because the value determined based on incineration provides a worst-case scenario with respect to greenhouse gas (GHG) 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: Butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid

CAS Registry Number: 125495-90-1

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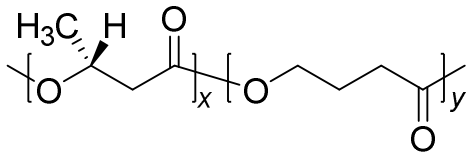
[1] *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed December 2022, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[2] *Id.*

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

[4] This is further supported by the United States Environmental Protection Agency's (EPA) *Advancing Sustainable Materials Management: Facts and Figures 2018*, accessed September 2022, 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 United States; plastics are not included among the materials reported to be composted.

Structural Formula:



$25\% \leq y \leq 35\%$

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 in blends with polyesters to fabricate all forms of food-contact articles, will be entirely incorporated into the finished food-contact article, and is expected to remain with these materials throughout use of the FCS in the 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.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal (*i.e.*, sanitary landfill or incineration). The FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has been calculated. The concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications.

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. GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (*see* Confidential Addendum to Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

EPA regulations require all 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 and Appendix 2). 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 aquatic or terrestrial environment when disposed 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 is not expected to 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 Item5, 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 Addendum to Environmental Assessment (**Attachment 15** of the FCN) 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 addendum, 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 EPA'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 ("Criteria for Municipal Solid Waste Landfills") 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 involves 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, 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 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 C. Skaggs, JD, MPH (Epidemiology and Biostatistics), Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Skaggs has 11 years of experience with environmental assessments for FCN submissions.

Kristin P. Wiglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Wiglesworth has over 5 years of experience performing evaluations relating to all aspects of preparing FCNs, and 16 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.

Kathryn C. Skaggs
Counsel for Notifier
Date: December 30, 2022

14. References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, United States Environmental Protection Agency, accessed December 2022, https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

15. Attachment

1. Confidential Addendum to Environmental Assessment