Environmental Assessment

1. Date: May 13, 2022

2. Name of Applicant/Notifier: Meredian, Inc.

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier:

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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), pentaerythritol (CAS Reg. No. 115-77-5), which has the molecular formula $C_5H_{12}O_4$ and the chemical formula $C(CH_2OH)_4$, when used in polyhydroxyalkanoate (PHA) polymers cleared under FCN 1398. The maximum use level of the FCS relative to total polymer in finished food-contact articles will not exceed 1.5%. The finished polymers containing the FCS will contact all foods, except alcoholic foods, under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)"), and low alcohol foods (up to 15% alcohol) under Conditions of Use E ("Room temperature filled and stored (no thermal treatment in the container)") through G.

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. 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 disposed, 16.9% was combusted, 13.6% was recovered for recycling.[1] As the FCS is used in a resin that is expected to be disposed primarily by land-filling or combustion (*i.e.,* not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.6% of food-contact materials containing the FCS will be combusted annually.[2]

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[1] *Advancing Sustainable Materials Management: 2018 Tables and Figures*, U.S. Environmental Protection Agency, December 2020, Table 8 (Plastics in Products in MSW, 2018), page 10, accessed March 2022, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

[2] 16.9% combusted ÷ (16.9% combusted + 69.4% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

Food-contact materials containing the FCS may ultimately be subject to composting because PHA polymers 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.[3] 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 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 composting of food-contact materials containing the FCS occur, the Notifier does not expect this to adversely impact the environment.[4]

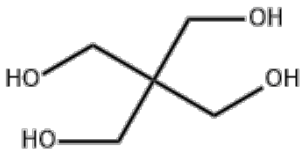
5. Identification of the Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is pentaerythritol (CAS Reg. No. 115-77-5), which has the molecular formula $C_5H_{12}O_4$ and the chemical formula $C(CH_2OH)_4$.

Chemical Abstracts Service (CAS) name: 2,2-Bis(hydroxymethyl)-1,3-propanediol

CAS Registry Number: 115-77-5

Structural Formula:



Physical Description of FCS:

Physical Form: white solid

Melting Point: 260°C

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[3] This is further supported by the Environmental Protection Agency's (EPA) *Advancing Sustainable Materials Management: 2018 Tables and Figures*, U.S. Environmental Protection Agency, December 2020, Table 24 (Products Recycled, Composted and Managed by Other Food Pathways in the Municipal Solid Waste Stream, 1960 To 2018), 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. *See* Table 24, page 38, accessed March 2022, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

[4] *See* EPA's *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Material Generation and Management in the United States*, December 2020, accessed March 2022, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

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 food-contact materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); 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 International Trade in Endangered Species of Wild Fauna and Flora* to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. 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. In these applications, the FCS (*i.e.*, an additive for PHA polymers) is expected to be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as a part of the food-contact material manufacturer's overall nonhazardous solid waste in accordance with established procedures.

The subject FCS consists of the elements carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment, and an assessment of these worst-case releases is also included in the same confidential appendix.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency ("U.S. EPA") under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Moreover, 40 C.F.R. § 1508.27(b)(10) states that when evaluating 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." 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 Attachment 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.

Only extremely small amounts, if any, of the substances from the finished food-contact materials containing the FCS are expected to enter the environment as result of landfill disposal, 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 groundwater monitoring systems. Even if a very small amount of substances leach from the landfilled food-contact material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with this FCS.

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 subject 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 in terrestrial ecosystems are anticipated as a result of the proposed use of the subject 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 subject FCS in the manufacture of food-contact articles and packaging intended for use in contact with food.

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 (*e.g.*, petroleum products, coal, etc.). 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 it will replace use of other additives.

Manufacture of the FCS, its use in PHA polymers, and the final conversion to finished food-contact articles and packaging will consume energy and resources in amounts comparable to the manufacture and use of other additives. Articles and packaging materials produced from PHA polymers containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. Thus, there will be no impact on current recycling programs. Importantly, PHA polymers containing the FCS are not recycled and would instead be removed from the recycling stream based on source control procedures.[5]

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 mitigation is required.

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 significant impact.

12. List of Preparers

Mark Thompson, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over twelve years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Eight years of experience preparing FCN submissions, including their Environmental Assessments

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[5] *See* NatureWorks LLC, "Using Near-Infrared Sorting to Recycle PLA Bottles," at: https://www.natureworksllc.com/~/media/The_Ingeo_Journey/EndofLife_Options/mech_recycling/20090708_NatureWorks_UsingNIRSortingtoRecyclePLABottles_pdf, detailing a method for sorting biopolymers from traditional plastic resins.

13. Certification

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

Mark Thompson
Counsel for the Notifier
Date: May 13, 2022

14. References

1. *Advancing Sustainable Materials Management: 2018 Tables and Figures*, U.S. Environmental Protection Agency, December 2020, available at the following website: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.
2. NatureWorks LLC, "Using Near-Infrared Sorting to Recycle PLA Bottles," at: https://www.natureworksllc.com/~/media/The_Ingeo_Journey/EndofLife_Options/mech_recycling/20090708_NatureWorks_UsingNIRSortingtoRecyclePLABottles_pdf, detailing a method for sorting biopolymers from traditional plastic resins.

15. Appendices

1. Confidential Environmental Information