Environmental Assessment

1. Date November 25, 2013

2. Name of Applicant/Petitioner Meredian, Inc.

3. Address All communications on this matter are to be sent in care of Counsel for Notifier:
Devon Wm. Hill, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, D.C. 20001
Telephone: 202-434-4279
E-mail: hill@khlaw.com

4. Description of Proposed Action:

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), a polymer of 3-hydroxybutyrate with 3-hydroxyvalerate, 3-hydroxyhexanoate, 3-hydroxyoctanoate, and/or 3-hydroxydecanoate, when used in the manufacture of food-contact materials. The primary end-use applications for the polymer are houseware applications, such as disposable cutlery and utensils, outer plastic bags, and other disposable containers. Other applications may include films, coatings, and thermoformed or injection molded articles. The FCS is intended for use in contact with all food types as set forth in 21 C.F.R. § 176.170(c), Table 1, under Conditions of Use B through H, as set forth in § 176.170(c), Table 2.

The FCS offers significant improvements as compared with other, similar polymers including other polyhydroxyalkanoate (PHA) polymers. The FCS combines the thermomechanical properties of polyolefins with the physicochemical properties of polyesters. Inclusion of the medium chain length side groups leads to desirable changes in the physical properties as compared to the more familiar PHA products including 3-hydroxybutyrate homopolymer or copolymers of 3-hydroxybutyrate with 3-hydroxyvalerate. These changes include an increase in flexibility and ductility, which allows the FCS to be used in films and other non-rigid articles.

Another advantage of the FCS is that it is a biopolymer that may serve as an alternative to the petroleum based polymers currently used to produce food packaging and single service cutlery and utensils. The FCS is shelf stable, and will not begin to biodegrade until it is exposed to microbial enzymes in soil, compost or marine environments. Further, the reduction in crystallinity imparted by the inclusion of the medium chain length side groups serves to increase the rate of degradation when in the presence of microbial enzymes.

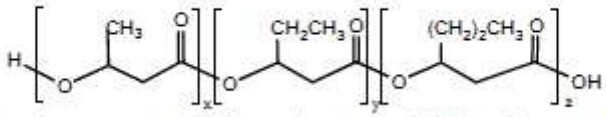
Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2010, approximately 54.2% of municipal solids waste is currently

deposited in land disposal sites, 11.7% is combusted, and 34.1% is recovered (a combination of waste recovered for recycling and for composting). Of the latter value, approximately 64.9% constitutes materials that were recycled and 20.2% consists of materials that were composted.[1] The Notifier does not anticipate that materials containing the FCS will be recycled, as it is intended for use in applications that are not significantly subject to recycling. More specifically, the FCS will not be used in the manufacture of beverage containers or other blow-molded articles. Materials composed of the FCS may be composted because the product is biodegradable. Programs that seek to compost quick service food contact materials, such as cutlery and containers, are becoming more prevalent; nevertheless, the Notifier anticipates that only a small fraction of the products that are disposed of will be directed to official composting programs. Therefore, the majority of the materials containing the FCS will be land-disposed and combusted.

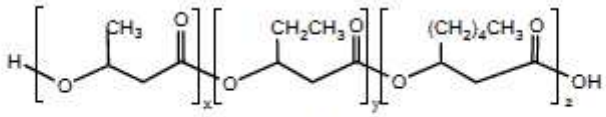
5. Identification of the Subject of the Proposed Action

The subject of this notification is a polymer of 3-hydroxybutyrate with up to 25% of 3-hydroxyvalerate, 3-hydroxyhexanoate, 3-hydroxyoctanoate, and/or 3-hydroxydecanoate.

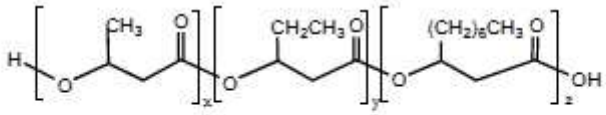
The FCS does not have a CAS Registry Number or Index name. The FCS is a random copolymer in which 3-hydroxybutyrate units represent approximately 75% of the polymer, with the 3-hydroxyvalerate, 3-hydroxyhexanoate, 3-hydroxyoctanoate, and/or 3-hydroxydecanoate monomer units representing up to 25% of the polymer. Because the FCS is a random copolymer, a single chemical structure cannot be provided; however, the various polymer repeating units formed by the reaction of the starting monomers may be depicted as follows:



polyhydroxybutyrate-co-polyhydroxyvalerate-co-polyhydroxyhexanoate PHBVHx



polyhydroxybutyrate-co-polyhydroxyvalerate-co-polyhydroxyoctanoate PHBVO



polyhydroxybutyrate-co-polyhydroxyvalerate-co-polyhydroxydecanoate PHBVD

[1] *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2010;* EPA-530-F-11-005, November 2011. U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), Washington, DC, 20460. See http://www.epa.gov/osw/nonhaz/municipal/pubs/msw_2010_rev_factsheet.pdf.

6. Introduction of Substances into the Environment

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicating any adverse environmental impact as a result of the manufacture of the subject polymer. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here. Information on the impacts relating to the source material is provided in the confidential attachment to this EA.

No environmental release is expected when the subject polymer is used in the manufacture of packaging materials. The polymer will be entirely incorporated into the finished article. Any waste material generated in this process, e.g., plant scraps, is expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Food-contact materials manufactured using the subject polymer are expected to be disposed of either by conventional rubbish disposal (i.e., sanitary landfill) or incineration. Use of commercial compost sites also is a viable disposal option, but is not expected to be the typical method of disposal. The subject copolymers consist of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

Only extremely small amounts, if any, of the polymer's constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) 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, as well as groundwater monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

If finished food-contact materials made with the FCS are introduced into commercial composting sites, the polymer is expected to biodegrade. In this regard, the FCS has been shown to fulfill the evaluation criteria for material characteristics, biodegradation, disintegration and compost quality as defined in ASTM D6400-04[2] and EN13432 (2000). The FCS has also received the Vincotte certifications "OK Compost," "OK Compost Home," "OK Biodegradable Water," and "OK Biodegradable Soil."[3]

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[2] *See* attached Certificate from the Biodegradable Produce Institute, included as Appendix A to this EA.

[3] *See* www.vincotte.com. A rating of "OK" is a 4-star rating defined by 80-100% biodegradability/compostability. The certificates are included as Appendix A to this EA.

The FCS has been determined to be completely degradable under mesophilic anaerobic conditions,[4] as well as aerobic marine conditions,[5] based on ASTM D5511 and ASTM 6691-09, respectively. The FCS was also shown to be disintegrable under aerobic marine conditions per ASTM D7081-05.[6]

7. Fate of Emitted Subjects in the Environment

a. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The polymer is of high molecular weight and does not volatilize.

The products of complete combustion of the polymer would be carbon dioxide and water; 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.

b. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to its proposed use. No significant quantities of any substance will be added to these water systems upon proper incineration of the polymer, nor upon its disposal in landfills, due to the extremely low levels of aqueous migration of polymer components.

While not relevant to the intended application of the FCS as no exposure to water is anticipated, the FCS has been tested for aquatic toxicity. Based on an $EC_{50} > 10$ g/L, the FCS is not toxic to *Daphnia Magna*.[7]

c. Land

Considering the factors discussed above, no significant effects on exposure to any FCS-derived substance in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. No significant quantities of any substance will be added to these environments upon

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[4] *See* Organic Waste Systems Final Report High Solids Anaerobic Digestion Under Mesophilic Conditions of PHA 90809A, Study PHVT-3/1, dated March 27, 2012, included as Confidential Appendix B to this EA.

[5] *See* Organic Waste Systems Final Report Marine Aerobic Biodegradation Test of PHA 90809A, Study PHVT-1/2, included as Confidential Appendix C to this EA.

[6] *See* Organic Waste Systems Final Report Marine Disintegration Test of PHA 90809A, Study PHVT-4, included as Confidential Appendix D to this EA.

[7] *See* Organic Waste Systems Final Report Aquatic Invertebrate Acute Toxicity Test Freshwater Daphnids on PHA 90809A, Study PHVT-5, dated January 17, 2013, in Confidential Appendix E to this EA.

proper incineration of the polymer, nor upon its disposal in landfills, due to the very low levels of migration of polymer components.

Moreover, it is not expected that the presence of the FCS in controlled commercial composting sites will result in the release of adverse substances into terrestrial ecosystems. The FCS exhibited complete disintegration at the end of 12 weeks under controlled commercial composting conditions.[8]

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 articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of very small quantities of combustion products and extractables. There may be some minor products of commercial composting. None of these potential releases presents any toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS.

In this regard, the compost generated in the compostability testing program on the FCS was subjected to ecotoxicity testing; no adverse ecotoxicity was observed in barley (plant growth) and water cress (seed germination) studies.[9]

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 polymer.

9. Use of Resources and Energy

The FCS is a bio-based polymer, produced from sugar in the growth phase and triacylglycerols in the PHA polymer accumulation phase. A discussion of the use of resources from the feedstock is provided in Confidential Appendix F to this EA. With regard to energy use, as with other food packaging materials, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products and coal. The Notifier's FCS is expected to compete with, and to some degree replace, similar food contact polymers already on the market, such as polystyrene, polyolefins, and polylactic acid (PLA). In terms of the use of energy and resources for these polymers, the production of the PHA polymer is expected to be

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[8] *See* Organic Waste Systems Final Report Pilot-Scale Composting + Sieving Test for Measurement of Disintegration of PHA 90809A, Study PHVT-1/3, included as Confidential Appendix C to this EA.

[9] *See* Organic Waste Systems Barley Plant Growth Test Compost Residuals of PHA 90809A, Report PHVT-1/4, and Cress Test on Compost Residuals of PHA 90809A, Report PHVT-1/5, included as Confidential Appendix C to this EA.

most similar to the production of PLA polymers, because lactic acid monomer is produced through fermentation of foodstuffs. There is relatively little similarity (or equivalence) in the production of PHA as compared to polystyrene or polyolefins. Overall, the fermentation process used in PHA production is, in fact, much closer to wine and beer making, rather than the chemical synthesis of conventional plastics. The raw material for PHA is plant-based triacylglycerol, as compared to the derivatives of petroleum. Polystyrene and polyolefins are produced in high temperature, high pressure environments, which would be expected to require greater energy usage than is needed for the PHA fermentation process. Therefore, the partial replacement of such polymers by the Notifier's FCS is not expected to have any adverse impact on the use of energy and resources.

Packaging materials produced from the subject polymer are expected to be disposed of according to the same patterns as used with currently available materials. The FCS is intended primarily for use in quick service applications for which there is no recycling stream, nor do consumers expect to recycle such materials. For example, the FCS is intended for single use disposal utensils, plates, clamshells, and home storage bags, none of which are intended to be recycled. The FCS is not intended for use in the production of articles that are commonly recycled, such as bottles that would compete with, for example, the polyethylene terephthalate (PET) bottle market. Current competitive products (i.e., utensils, plates, etc.) are manufactured using polystyrene, polyolefins, and PLA. However, none of these types of products are recycled, and any items that inadvertently end up in the process stream should be easily removed as part of every company's source control practices.

Indeed, in its *Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations,* FDA recommends that recyclers implement "controls on the source of the post-consumer polymer, adequate sorting procedures for the incoming post-consumer material, use limitations on the finished recycled packaging (such as use at room temperature or below), or food-type restrictions (such as dry or aqueous foods only)."[10] When companies are submitting requests to FDA for No Objection Letters (NOL) on their recycling processes, they are supposed to submit "a description of the source of the recyclable plastic and a description of any source controls in place intended to ensure that only plastic that initially complied with the applicable regulations is recycled." Moreover, the emergence of next generation near-infrared recycling equipment is enabling the sorting of plastics using each material's unique spectral signature. This technology facilitates the effective separation of petroleum-based plastics as well as biopolymers such as PHA. For these reasons, the FCS is not expected to have any effect on commercial recycling processes.

[10] *See* FDA's *Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations* (August 2006), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm120762.htm.

10. Mitigation Measures

The intended use of the FCS is not reasonably expected to create new environmental problem that would require mitigation measures of any kind. As discussed above, the use and disposal of food-contact materials fabricated from the FCS is not expected to result in significant adverse environmental impacts. This is primarily due to the very low levels of potential migrants that could leach from the finished article, the insignificant impact on environmental concentrations from the polymer's combustion products, the lack of adverse effects of composting, and the reduced environmental footprint of the subject polymer to the materials it is intended to replace.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no environmental impact. Considering the excellent properties of the FCS for use in food-contact applications, the fact that its constituents are not expected to enter the environment in more than minute quantities upon use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective FCN to permit the use of the subject polymer as described herein is environmentally safe in every respect.

12. List of Preparers

Devon Wm. Hill, Partner, Keller and Heckman LLP

Jason P. Schmidt, Ph.D., Scientist, Keller and Heckman LLP

13. Certification

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

Date: November 25, 2013

Devon Wm. Hill

Keller and Heckman LLP