Part IV – Environmental Impact of Food Contact Substance (21 CFR part 25)

B. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 CFR 25.31(a), using the abbreviated format described in (b)(1).

Environmental Assessment in Support of the Food Contact Notification for *Blend of butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid, and butanoic acid, 3-hydroxy-, (3R)-, homopolymer.*

1. Date: September 20, 2011
2. Name of submitter: Telles LLC
3. Business address of submitter: 650 Suffolk Street, Suite 100, Lowell, MA 01854-3639
4. Description of the proposed action:
    a. Requested action: Food contact notification for *Blend of butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid (CAS Reg. No. 125495-90-1), and butanoic acid, 3-hydroxy-, (3R)-, homopolymer (CAS Reg. No. 29435-48-1)*, (trade name [redacted]™), which will be used in finished food-contact articles including, but not limited to, coatings for paper and paperboard, films, and foamed and molded articles.

    b. Need for action: Food-contact substances (FCS), as defined in the Federal Food, Drug, and Cosmetic Act, are eligible to be the subject of a food-contact notification (FCN) for review by FDA leading to an effective FCN after 120 days from filing if FDA finds that the FCN demonstrates the safety to a reasonable certainty for the intended use of the FCS.

    The utility of [redacted] biodegradable polymers is quite clear. Specifically, [redacted] polymers are useful in the following applications:

    - **Film grade** (for blown and cast film applications, including packaging)
    - **Injection grade:** Can replace polystyrene or polypropylene for use in many consumer retail products and high-performance applications
    - **Extrusion sheet and thermoforming grade:** Can be used for storage containers
    - **Developmental grades** (for foam, blow molding, non-woven, and monofilament): Can be used for a variety of products, including containers and bottles, personal care and hygiene products, and safe shipping and packing materials.

By way of additional support for the utility of [redacted], we note that the polymers are unique high-performance bioplastic alternatives for food packaging and food-service containers and utensils. The key features of [redacted] polymers include heat and moisture resistance, durability, and the ability to be processed on existing equipment. Because of these properties, [redacted] can replace many petroleum-based plastic materials, from olefins and styrenics to ABS and polycarbonate.

Products made with [redacted] high-performance bioplastic can be stored for extended periods, and they will not begin to biodegrade until they are exposed to environments where there is microbial activity, such as soil, home compost, industrial compost, or marine environments. [redacted] is a remarkable high-performance bioplastic that is applicable for almost any industry, and it is a practical alternative for applications where many conventional plastics are currently in use.

c. Locations of use/disposal: Articles made with the FCS may be used wherever food is consumed including, but not limited to, homes and restaurants or other foodservice outlets. Initial disposal will occur at these sites, with subsequent disposal in landfills or by composting (the polymer is biodegradable) or recycling, according to where the various disposal alternatives are available.

The Submitter does not anticipate producing finished food-contact articles from the subject [redacted] polymers. The Submitter anticipates producing and selling [redacted] polymers to other companies, which will use the polymers to produce food-contact articles. Food-contact articles produced with the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Based on previous research in the 1990s, about 76% of the articles made from the FCS will be deposited in land disposal sites, and about 24% will be combusted.[1]

Given the biodegradability of the FCS, however, articles made with it may be composted. In responding to PNC 796, the FDA has stated as follows with respect to the Agency's doubts about composting as a method of disposal of the FCS: "We believe that composting of food-contact materials because of its biodegradability is not a significant resource management option for disposal of the FCS." FDA has not cited any factual basis for this opinion. In fact, composting may be a useful alternative method of disposal of articles made with the FCN when the articles are disposed of at food-service establishments, which can aggregate used articles for composting on an economical scale or may choose to conduct composting for other reasons. Furthermore, composting is an option for disposal of food-contact articles made with [redacted] at the household and community level as well. The extent of such composting alternatives cannot be predicted with assurance at this time because compostable materials such as [redacted] are only beginning to come onto the market. Nevertheless, composting should not be ignored by FDA as an option for postconsumer disposal of food- contact articles made with [redacted], since its biodegradability makes composting a technologically feasible alternative.

It is very significant that [redacted] resins are the only non-starch materials to receive all four Vincotte certifications for biodegradability in natural soil and natural water environments, industrial composting units, and home composting systems. Vincotte is a global company providing inspection, monitoring, and certification services, analyses and testing in many areas, including environmental protection. Additional information on Vincotte can be found on its website at www.vincotte.com.

Attached are the Vincotte certifications of [redacted] for home compostability and biodegradability in fresh water, and the Metabolix confirmation of biodegradability in the marine environment. In support of these certifications and conclusions and the lack of significant environmental impact from disposal of articles made with [redacted], also attached are reports showing "heavy metals" far below the limits of ASTM 0 6400-04 and EN 13432 and the absence of [redacted] toxicity to Daphnia.

It also is possible that articles made with [redacted] polymers may be recycled. As with all materials, the development of recycling for articles made from [redacted] will require the presence of a critical mass of such articles in the market and in the post-consumer recycling stream. Also, as with all new materials, there is no way to predict at this time whether or when such a critical mass of [redacted] food-contact articles will materialize.

Whether or not articles made with [redacted] are recycled, there is no basis for concern that such articles will interfere with recycling of post-consumer food containers made from other substances. The only food containers which are recycled to an appreciable extent are made from polyethylene terephthalate (PET) (primarily soda, water, and beer containers) and high-density polyethylene (HDPE) (primarily milk and household cleaning products, with the latter of course not being subject to FDA's jurisdiction). [redacted] is a versatile material, including the capability of being blow-molded, so it is possible that it may find some applications which currently are filled by PET or PE. On the other hand, [redacted] will have many other applications, such as molded food utensils and non-bottle food-contact articles including cups, clamshells, and plates. These articles are disposed of almost entirely by land disposal or combustion, not by recycling. To the extent that any of these recyclable or non-recyclable articles are disposed of by littering instead of appropriate disposal, [redacted] presents the advantage of biodegradability.

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

   a. CAS name: Butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid; Butanoic acid, 3-hydroxy-,(3R)-, homopolymer acid

   b. CAS registration number: 125495-90-1; 29435-48-1

c. Molecular weight: minimum 300,000 Daltons

d. Molecular formula: Copolymer is produced by *in situ* fermentative polymerization of monomers produced through metabolic conversion of D-glucose to 3-hydroxybutyrate and metabolic oxidation of 1,4-butanediol to 4-hydroxybutyrate.The following are examples of typical formulations for food-contact applications:

[redacted] M1200 – 100% 3HB + 0% 4HB

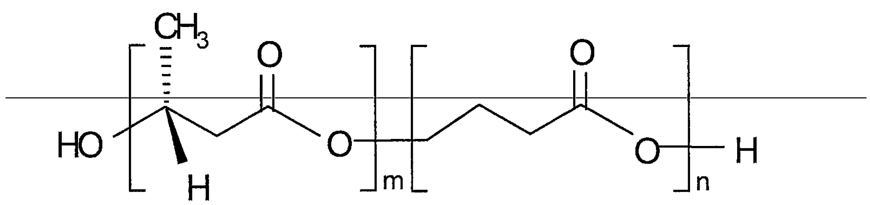
[redacted] M2100 – 95.6% 3HB + 4.4% 4HB

[redacted] M2200 – 91.2% 3HB + 8.8% 4HB

[redacted] M4100 – 84.2% 3HB + 15.8% 4HB

[redacted] M4200 – 81.5% 3HB + 18.5% 4HB

e. Structural (graphic) formula:



Blend of butanoic acid, 3-hydroxy- (3R)-, polymer with 4-hydroxybutanoic acid, and butanoic acid, 3-hydroxy-, (3R)-, homopolymer

CAS Registry Number: 125495-90-1; 29435-48-1

f. Physical description:

M1200
Glass Transition Point (Tg) Max: -3°C, Min: -15°C
Melting Point (Tm) Max: 180°C, Min: 150 °C
Molecular Weight (Mw): Min: 370,000 Da
Polydispersity (Mw/Mn): Max. 1.85, Min. 1.60

M2100
Glass Transition Point (Tg) Max: -3°C, Min: -15°C
Melting Point (Tm) Max: 180°C, Min: 150 °C
Molecular Weight (Mw): Min: 370,000 Da
Polydispersity (Mw/Mn): Max. 1.85, Min. 1.60

M2200
Glass Transition Point (Tg) Max: -3°C, Min: -15°C

Melting Point (Tm) Max: 180°C, Min: 150 °C
Molecular Weight (Mw): Min: 370,000 Da
Polydispersity (Mw/Mn): Max. 1.85, Min. 1.60

M4100
Glass Transition Point (Tg) Max: -3°C, Min: -15°C
Melting Point (Tm) Max: 180°C, Min: 150 °C
Molecular Weight (Mw): Min: 380,000 Da
Polydispersity (Mw/Mn): Max. 2.00, Min. 1.55

M4200
Glass Transition Point (Tg) Max: -3°C, Min: -15°C
Melting Point (Tm) Max: 180°C, Min: 150 °C
Molecular Weight (Mw): Min: 370,000 Da
Polydispersity (Mw/Mn): Max. 2.00, Min. 1.55

6. Introduction of substances into the environment:

   a. Introduction of substances into the environment as a result of manufacture:

      The FCN contains a detailed and comprehensive description of the manufacturing process for the [redacted] resins. The Submitter incorporates that description by reference in response to this portion of the Environmental Assessment.

      Under 21 C.F.R. 25.40(a), however, an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal after use, rather than the production, of FDA-regulated articles. This is a sensible approach since the manufacture of food-contact materials, like the manufacture of other products, is subject to comprehensive local, state, and Federal environmental regulation and oversight.

      To the best of our knowledge, there are no extraordinary circumstances which would require a departure from FDA's general rule that information about environmental introductions from the manufacture of food-contact substances is not required. Indeed, the production of [redacted] is subject to comprehensive environmental regulation, as is the production of all other food-contact materials. As the FDA has done with respect to another biopolymer (see FCNs 178, 475, and 594), we ask the Agency to remain consistent with its regulations, guidance, and practice. As an example of the comprehensive federal and state regulation which precludes a significant environmental impact from the manufacture of the FCS, we note that biomass residue from manufacture is permitted to be used as boiler fuel under Permit No. 05-A-313-P issued by the Iowa Department of Natural Resources. This permit was issued to ADM for its Clinton, Iowa facility where the FCS will be produced.

   b. Introduction of substances into the environment as a result of use/disposal:

The identity and potential levels of environmental introduction of components of the polymer are confidential business information, which are provided in a separate confidential appendix to this EA. The information in the confidential appendix demonstrates that the disposal of articles made with this polymer will not result in the significant introduction of any substances into the environment.

The primary location of disposal is expected to be landfills, which are designed and operated to avoid migration of landfill contents into the environment. 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 (40 CFR § 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 take corrective action as appropriate. To the extent disposal involves recycling or composting, the absence of available migrants and the environmental regulations governing recycling and composting operations also will avoid significant introduction of substances into the environment.

7. Fate of substances released into the environment:

   Since there will be no significant release of substances into the environment, as discussed above and in the confidential appendix, we respectfully submit that it should not be necessary to-describe the fate of released substances. In support of this position, we also note again that [redacted] resins have received Vincotte certification of environmental suitability for industrial and home composting and biodegradability in soil and freshwater environments. In addition, the [redacted] resins comply with ASTM D7081 regarding biodegradability in marine environments.

8. Environmental effects of released substances:
   In accordance with Item 7, the absence of any potential significant release of substances into the environment eliminates the need to discuss the environmental effects of released substances. The Vincotte certifications and compliance with ASTM 07081 also eliminate any concern in this regard.

9. Use of resources and energy:
   This bio-based polymer, produced through the fermentation of sugar, will replace other polymers, which may be bio-based or sourced from petroleum, including PVC, PET, PP, ABS, and polycarbonate. There is no basis to expect any environmentally significant increase in the use of resources and energy from use and disposal of this polymer. In support of this conclusion, Submitter also incorporates by reference the description of the manufacturing process set forth in the FCN. FDA has requested information on the recycling of competitive materials. The only plastic with which [redacted] theoretically might compete and which is recycled to a significant extent is PET. The PET articles which are recycled significantly are bottles for soft drinks,

water, and beer. While the Submitter has high hopes for the success of [redacted] in the marketplace, it is highly unlikely that [redacted] will make significant inroads into the soft drink, water, or beer applications for PET in the reasonably foreseeable future. To the extent that [redacted] does make such inroads, resulting in a critical mass of [redacted] articles for collection and recycling, it is reasonable to expect that arrangements will be made to collect and recycle [redacted]. It should be noted that recycling includes the depolymerization and repolymerization of articles.

FDA previously asked about:

i. “patterns of land use (cultivation) and agricultural practices (fertilizers and pesticides) for deriving one of the sources of materials used to produce the FCS,
ii. consumption of water resources (steam production and wastewater treatment),
iii. disposal of biomass waste products (fermentation solids and gases),
iv. use and disposal from use of process aids (extractive solvents)."

With respect to effects on land use, agriculture, and use of water resources, there is no possibility that the production of this FCS could have a significant impact. The production of the food-contact substance (FCS) is an innovative technology. In topic 5, the EA reports that D-glucose (dextrose) is metabolically converted by fermentative polymerization into the FCS (see also a series of patents describing details about the process to produce and extract the FCS.[2] Because the primary feedstock, dextrose, is derived from corn,[3] the potential impact from land that may be converted into agricultural use for cultivation of corn to support the manufacture of the FCS needs consideration to determine whether any extraordinary circumstances exist consequent on the manufacturing capacity and commercial demand.

The FCS will be produced in a commercial scale plant at Clinton, IA.[4] Environmental considerations of the context and intensity of localized effects, specifically, changes in land use in Iowa, establish "the significance of an action" on the "the affected region, the affected interests, and locality." [5] If we assume all corn available for refining to support the manufacture of the FCS is locally from IA, then we can estimate the percentage of current land use devoted to cultivate the quantity of corn needed for manufacture of the FCS. The estimation is based on 1) a public disclosure that the annual production capacity of the facility in Clinton, lA, is about 110 million pounds, 2) a public presentation of research [6] from which the amount of corn required to produce one pound of FCS can be derived, 3) United States' agricultural data, [7] and 4) corn industry statistics. [8] A rudimentary estimation is calculated below.

- **Amount of corn needed annually to support production of the FCS:**
  110 x 10^6 lbs FCS/year *(see endnote 4)* X 5 lbs corn/lb FCS (a derived statistic *(see endnote 6)* for the amount of corn required to produce one pound of FCS) = 550 x 10^6 lbs corn/year
- **Area of corn required to support the manufacture of the FCS:**
  550 x 10^6 lbs corn/year x 1 bu corn/70 lbs corn *(see endnote 7)* x 1 acre/166 bu corn *(see endnotes 7 & 8)* = about 60,000 acres

- **Percentage of land use to support the manufacture of the FCS:**
  60,000 acres/12.6 x 10^6 acres (land used to cultivate corn in IA) *(see endnote 7)* x 100% = about 0.5%

Therefore, we understand that, because only about 0.50/0 or less of currently cultivated land is needed to support the anticipated manufacturing capacity and near-future commercial demand of the FCS, the proposed action is not anticipated to alter significantly land use. Moreover, we understand that, because the increase, if any, of land area to cultivate corn is small, the environmental burdens associated with corn cultivation, which include concomitant use of resources (for example, water or chemical fertilizers and other agricultural materials) and energy (direct and indirect), are also not anticipated to increase significantly to accommodate the demand placed upon corn as a raw source of manufacturing feedstock for the FCS.

A consideration about compostability of the FCS is not a significant basis for the agency to make its final environmental decision because, as stated in the EA, the ultimate disposal location after use of the FCS is primarily in landfills. Without a compulsory or an incentive-based collection system for the FCS at the end of its service life, compostability is a minor consideration.

The EA proposes that the FCS holds promise for commercial applications because its polymeric characteristics are functionally equivalent to synthetic petrochemical-based plastics that presently dominate the commodity plastics' market. Nonetheless, the EA recognizes that commercial development and demand of the FCS as an alternative to petrochemical-based plastics is not yet certain, and the projected market is focused on presenting the FCS "as a premium priced specialty material catering to customers who want to match the functionality of petroleum-based plastic but add the dimension of environmental responsibility to their products and brands.”[9]

Thus, the extent of environmental impact, if any, is related to added economic value for the FCS as a finished product. The environmental impact, which stems chiefly from raw material production and fermentative manufacturing processes, is moderated or inhibited by the acknowledged expense of the FCS, which is three-fold more expensive than petrochemical plastics. *(see endnote 9)* Therefore, any relative environmental advantages described in the EA about the FCS contrasted with competitive petrochemical plastics is correspondingly inhibited as well.

In addition, it should be noted that the subject of this EA is only the food-contact applications of the [redacted] polymers. The polymers have other uses which are not subject to FDA regulation. All of the information presented in the FCN and in the EA demonstrates that there will not be any significant environmental impact from [redacted] resins to the extent that they are subject to FDA regulation under this FCN.

10. Mitigation measures:

    There is no need for mitigation measures since there is no indication of any significant environmental impact from the use and disposal of this polymer.

11. Alternatives to the proposed action:

The only alternative is rejection of this FCN. That alternative would not have any environmental benefit since the current food-packaging materials would continue to be used and disposed of, to the exclusion of this polymer, which will not bring any significant release of substances into the environment.

12. List of preparers:
    Xiudong Sun, Telles Product Steward
    Naeem Mady, Intertek VP of Regulatory

13. Certification:
    The undersigned official certifies that the information presented is true, accurate, and complete to the best of my knowledge.

Date: 9/22/14

Signature: [redacted]

Printed name: Robert Engle, General Manager

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[1] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC, 20460, May 1998.
[2] For example, to produce the polymer, see GW Huisman, FA Skraly, DP Martin,
and OP Peoples, US Patent 7229804 (June 12, 2007), "Biological systems for manufacture of polyhdroxyalkanoate polymers containing 4-hydroxyacids," and, to extract the polymer, see J Van Walsen, L Zhong, and SS Shih, US Patent 7252980 (August 7, 2007), "Polymer extraction methods."
[3] S Kim and BE Dale, "Life cycle assessment study of biopolymers (polyhydroxyalkanoates) derived from no-tilled corn," Int J LCA, 10(3), 200-210 (2005).
[4] Metabolix, Inc., Annual Report on Form 10-K for fiscal year 2007 filed March 13, 2008, with the United States Securities and Exchange Commission.
[5] 40 Code of Federal Regulations 1508.27.
[6] S Kim and BE Dale, "Life cycle assessment of integrated biorefinery-cropping systems: all biomass is local, 11 in Agriculture as a Producer and Consumer of Energy, JL Oulaw, KJ Collins, and JA Duffield (Eds.), CAB International,
Wallingford, Oxfordshire, UK, 2005, conference proceedings of Farm Foundation and USDA Office of Energy Policy and New Uses, Arlington, VA, June 24-25, 2004.
[7] United States Department of Agriculture, Agricultural Statistics, 2008, National Agricultural Statistics Service, United States Government Printing Office, Washington, DC, 20402 (2008).
[8] Corn Refiners Association, Corn: Part of a Sustainable Environment, Corn Refiners Association Annual Report 2006, Washington, DC, 20006
[9] BE DiGregorio, *Chemistry & Biology*, 16(1), 1-2 (2009), “Biobased performance bioplastic: Mirel.”