Environmental Assessment

1. Date: October 12, 2018

2. Name of Notifier: Total Corbion PLA bv

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier,
Mitchell Cheeseman, Ph.D.
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4. Description of the Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (known as Polylactide (PLA) polymers), optionally containing up to 16 weight percent D-lactic acid polymer units (High D PLA; CAS Reg. No. 9051-89-2), made by Total Corbion PLA, as a component of food-contact articles in contact with all types of food under Condition of Use B through H.

The subject polymer offers several technical properties that make it useful in a variety of food contact applications. The thermal and mechanical properties of this polymer make it useful in flexible packaging and in certain rigid packaging applications.

The Notifier does not intend to produce finished food packaging materials from PLA but may manufacture films and sheets from PLA to be supplied as components for finished packaging. The polymer pellets, film, and sheets will be sold to manufacturers who produce food-contact materials. Those food-contact materials will be utilized in patterns corresponding to the national population density and will be widely distributed across the United States of America. Therefore, it is anticipated that disposal will occur nationwide, with material being land disposed, combusted, composted, or recycled. According to the U. S. Environmental Agency's (US EPA) 2015 update regarding municipal solid waste in the United States, 52.5% of municipal solid waste (MSW) generally was land disposed, 12.8% was combusted with energy recovery at permitted MSW combustion facilities, 8.9% was composted, and 25.8% was recovered for recycling.[1] As noted in this same US EPA MSW report, food-contact materials manufactured from PLA are not expected to be collected for recycling (see data excerpted from this report in the below table).

Table 1: 2015 Municipal Solid Waste Generation Data for PLA[2]

	Generation (US short tons)	Recovery (%)
PLA plastic in plates & cups	20,000	0
PLA plastic in other plastic packaging	10,000	0
Total	**30,000**	**0**

[1] US EPA Report: *Advancing Sustainable Materials Management: Tables and Figures 2015, Assessing Trends in Material Generation, Recycling Composting, Combustion with Energy Recovery and Landfilling in the United States. July* 2018. https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

[2] See footnote 1, Table 8, Plastics in Products in MSW, US EPA 2015.

Additionally, even though the FCS is compostable, these materials are not likely to be recovered for composting given that commercial composting (i.e., at monitored sites operating at the elevated temperatures, with mixing and aeration, etc.) is not a widely-used disposal option in the United States. Excluding these means of disposal and assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.4% of the materials will be deposited in land disposal sites and about 19.6% will be combusted.[3] Using these disposal rates and the EPA's 2015 MSW generation data for PLA provided in Table 1, we estimate the amount of PLA combusted and land disposed in 2015 was 5,333 and 21,904 metric tons (mT), respectively, as is shown below.

$$30{,}000 \text{ US short tons } \times \frac{0.907 \text{ mT}}{\text{US short ton}} = 27{,}210 \text{ mT PLA disposed}$$

$$19.6\% \text{ MSW combustion rate } \times 27{,}210 \text{mT PLA Disposed} = 5{,}333 \text{ mT PLA combusted}$$

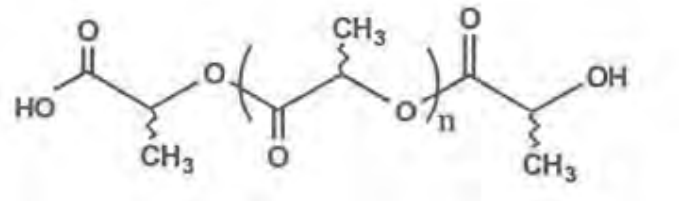
$$80.4\% \text{ MSW land disposal rate } \times 27{,}210 \text{mT PLA Disposed} = 21{,}904 \text{ mT PLA land disposed}$$

We anticipate that the FCS will replace a portion of this waste.

5. Identification of the Subject of the Proposed Action

The subject of this notification is (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (known as Polylactide (PLA) polymers), optionally containing up to 16 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2). Polylactide is a polymer of lactide, which is the cyclic dimer of lactic acid.

The structure may be represented as follows:



Property	**Value**[4]
Appearance	White solid
Melting point	150 – 230 °C
Decomposition Temperature	> 230 °C
Density	1.2 – 1.3 g/cm^3
Water solubility	insoluble

6. Introduction of Substances into the Environment

[3] 12.8% combusted ÷ (12.8% combusted + 52.5% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

[4] TOTAL CORBION PLA Company Safety Data Sheet, https://www.total-corbion.com/media/1066/sds-luminy-pla-neat-resin_en_23112017.pdf

Resulting from manufacture of the FCS:

Under 21 C.F.R. Section 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. Current information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact since the manufacture of PLA will not take place in the United States. Hence, information on the manufacturing site and compliance with relevant emission requirements is not provided in this Notification.

Resulting from use of the FCS:

No environmental release is expected based on the use of the subject polymer to fabricate food-contact materials. In these applications, the polymer will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process are expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Resulting from disposal of the FCS:

As noted previously, disposal by the ultimate consumer of food-contact materials produced with PLA will be by conventional trash disposal and primarily by sanitary landfill or incineration. Materials manufactured with the FCS may also be composted although as commercial composting of plastic polymers is not a widely-used disposal option in the U.S., we assume there are no environmental introductions resulting from commercial composting of materials manufactured with the FCS. Additionally, recycling of materials manufactured with the FCS is not anticipated.

We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this environmental assessment, to the annual municipal solid waste (MSW) production (262 million tons MSW in 2015), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled.[5] Further, the proposed use of the FCS and corresponding market volume (available in the confidential attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which was estimated to be 12.8% of the 262 million tons of total MSW generated (or 33.5 million tons) in 2015. Therefore, the FCS will not significantly alter the emissions from 40 CFR Part 60-compliant municipal solid waste combustion facilities, nor cause them to threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR 60 and/or other relevant state and local laws).

Land disposal: The FCS is composed of carbon, hydrogen and oxygen, elements that are commonly found in municipal solid waste. Under aerobic conditions, PLA decomposes to lactic acid and other smaller compounds, ultimately to carbon dioxide and water. Under anaerobic conditions and an aqueous medium, PLA will hydrolyze to lactic acid.[6] An unpublished report previously submitted to

[5] US EPA Report: *Advancing Sustainable Materials Management: Tables and Figures 2015, Assessing Trends in Material Generation, Recycling Composting, Combustion with Energy Recovery and Landfilling in the United States. July* 2018. https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

[6] Henton, D.E., et al, "Polylactic Acid Technology," in *Natural Fibers, Biopolymers, and Biocomposites*, Mohanty AK et al, eds. (2005).

FDA describing the hydrolysis kinetics of lactide indicates that the hydrolysis half-life of lactide at 25ºC is 3.3 hours in neutral and aqueous media.[7]

In light of EPA's regulations governing municipal solid waste landfills (40 C.F.R. Part 258), only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food contact articles manufactured with the FCS. 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. Landfills also are required to have ground-water monitoring systems. Although owners and operators of existing municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

Incineration: As we anticipate incineration of articles containing the FCS, and because the FCS, which has the molecular formula $(C_3H_4O_2)_x$, contains carbon and oxygen, we expect the release of carbon dioxide, a greenhouse gas (GHG).

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the 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 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 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."

Based on the confidential market volume, the expected annual carbon dioxide equivalent emission, as shown in the confidential attachment to the EA, is below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 C.F.R. Part 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 C.F.R. Part 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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 PLA. As indicated above in Item 6, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with PLA polymer. Carbon dioxide and water are the ultimate products of complete combustion of PLA. The concentrations of these two substances in the environment will not be significantly altered by the proper incineration of PLA in the amounts utilized for food-contact materials.

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 PLA. As

[7] Report, *Hydrolysis of Lactide in Aqueous and Acidic Media*, included as an Attachment to this EA.

indicated above in Item 6, no significant quantities of any substances will be added to these water systems upon the proper incineration of PLA, nor upon its disposal in landfills due to the regulations governing emissions from landfills.

C. Land: Considering the factors discussed above, no significant introductions of the FCS to terrestrial ecosystems are anticipated as a result of the proposed use and disposal of the subject polymer. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the low production of the FCS for use in food-contact applications, as evidenced by the market volume described in the confidential attachment, precludes any substantial release to the environment of the components. Finally, 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 inherent biodegradability, disintegration, and compostability as defined in ASTM D5338.92 and EN13432 (2000). Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Herein, we respectfully state that there is no reasonable expectation of a significant impact on any substance in the environment due to the proposed use of the FCS in articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the substances that may be released to the environment upon the use and disposal of food-contact articles made with PLA are extremely small quantities of combustion products and leachates, if any. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of PLA-containing food-contact articles. The use and disposal of PLA food-contact articles are not expected to violate applicable laws and regulations, e.g., the EPA regulations in 40 C.F.R. Parts 60 and 258. Finally, PLA exhibited complete disintegration under controlled composting conditions and the compost generated indicated no adverse ecotoxicity.

9. Use of Resource and Energy

The manufacture of food-contact articles using PLA manufactured by Total Corbion is not expected to result in a net increase in the use of energy and resources since the use of this PLA is intended to be used in place of other competitive PLA polymers, currently on the market to manufacture food packaging.

The replacement of these types of polymers by PLA is not expected to have any adverse impact on the use of energy and resources. This PLA is not manufactured in the United States, but its manufacture and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of the other polymers with similar physical properties. While PLA may be used to produce bottles, this substance will not be used in the manufacture of carbonated soft drinks. This is due to the fact that the transmission rate for carbon dioxide for PLA is substantially higher than that for polyethylene terephthalate (PET), the polymer primarily used for carbonated soft drink bottles. Therefore, the use of PLA will not have any impact on the recycling of containers used to package carbonated soft drinks. As previously noted, food-contact materials manufactured from PLA are not expected to be collected for recycling (please see table 1 of the EA).

One important difference between the manufacture of PLA and most other polymers is that PLA is not manufactured from petroleum derived substances as the basic raw material. It uses L-lactic acid, which is derived solely from the fermentation of sugarcane derived sugars. Sugarcane is currently the sole source of L-lactic acid and Total Corbion PLA does not intend to use alternative sources in the near future. Thus, the FCS is manufactured from a renewable source. In this regard, Section 101(b)(6) of the National Environmental Policy Act (NEPA) (42 U.S.C. Section 4331(b)(6)) states that:

> In order to carry out the policy set forth in this chapter, it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may…
>
> (6) enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources.

Thus, the replacement of other polymers by PLA will have a net decrease in the use of depletable resources. For all of the foregoing reasons, the use of the FCS as described in this Notification will not have an adverse impact on energy and resources.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles made from PLA. This is primarily due to the minute levels of potential migrants from the finished article, the insignificant impact on environmental concentrations of combustion products, and the use of renewable resources involved in the manufacture of PLA. Thus, the use of PLA is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

As no potential adverse environmental effects are identified, it is therefore unnecessary to propose alternative actions to that proposed in the Notification. If the proposed action is not approved, food packaging manufacturers would simply continue the use of those materials which this PLA would otherwise replace, resulting in no significant environmental impact.

12. List of Preparers

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Ave., NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011.

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has nine years of experience preparing environmental submissions to FDA for the use of food contact substances.

13. Certification

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

Date: October 12, 2018

[redacted]

Mitchell Cheeseman, PhD

14. References

Henton, D.E., et al, "Polylactic Acid Technology," in Natural Fibers, Biopolymers, and Biocomposites, Mohanty AK et al, eds. (2005).

Hydrolysis of Lactide in Aqueous and Acidic Media

TOTAL CORBION PLA Company Safety Data Sheet

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Tables and Figures*, December 2016.

15. Attachments

Confidential Attachment to the Environmental Assessment.
Hydrolysis of Lactide in Aqueous and Acidic Media