

1. **Date** February 3, 2016
2. **Name of Applicant/Notifier** PTT MCC Biochem Company Limited
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Pamela L. Langhorn, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Telephone: (202) 434-4291.
4. **Description of the Proposed Action**

The action requested in this Food Contact Notification (FCN) is clearance for the food contact substance (FCS), polybutylene succinate adipate cross-linked with malic acid, for use as a polymer in the manufacture of food-contact articles in contact with 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)”). Uses of the FCS include films, coatings, molded articles, and thermoformed articles. Examples of food packaging materials that may be prepared from the FCS include stand-alone films used as food wraps, coatings on paper and paperboard, laminate seals for flexible packaging, injection molded food-contact articles, and thermoformed food-contact articles such as food trays. The FCS is a soft and flexible polymer that provides greater adhesion strength compared to current polymers in the market place. In paper and paperboard specifically, the FCS is intended to provide a protective layer that prevents food from penetrating into the paper and paperboard structure, leading to soaking and reduced structural strength. The FCS will be used in single-use food-contact applications.

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials. Finished food-contact articles made with the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.¹ The types of environments

¹ *Advancing Sustainable Materials Management: Facts and Figures 2013. Assessing Trends in Materials Generation, Recycling and Disposal in the United States*, EPA530-R-15-003, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), June 2015, available at <http://www.epa.gov/solidwaste/nonhaz/municipal/msw99.htm>.

According to this report, of the total of 254.1 million tons of municipal solid waste (MSW) generated in 2013, 52.8% generally was land disposed, 12.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As the food contact substance (FCS) 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

(footnote continued)

present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared using the FCS.

5. Identification of Substance That Is the Subject of the Proposed Action

The FCS that is the subject of this Notification is a polybutylene succinate adipate cross-linked with malic acid. The FCS is prepared by the reaction of 1,4-butanediol, succinic acid, adipic acid, and malic acid.

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 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 as a result of the manufacture of the FCS. Specifically, as set forth in FDA's guidance,² extraordinary circumstances include situations where 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action 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. To the best of the knowledge of the Notifier, no situations such as these apply to the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No introduction of the FCS into the environment is expected to occur as a result of its intended use. The FCS is expected to be used as a polymer film, coating, or article to fabricate food-contact articles, and will be entirely incorporated into the finished food-contact article. Any

packaging materials containing the FCS will be combusted annually. This amount is calculated as follows:

$12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

² *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition*, Food and Drug Administration, May 2006, at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.

waste materials generated in this process (*e.g.*, plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced with the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen, and oxygen – elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide and water. Based on the proposed use of the FCS and its expected market volume,³ we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted. A new revised draft guidance document released by the Council on Environmental Quality (CEQ) in December 2014 states that a quantitative analysis of emitted carbon dioxide should be carried out where the emission will exceed 25,000 metric tons.⁴ The expected carbon dioxide emissions are below 25,000 metric tons per year as presented in our confidential attachment to this Environmental Assessment. Therefore, in accordance with the Council on Environmental Quality's (CEQ) revised draft guidance on greenhouse emissions and climate change impacts, for annual emissions falling below 25,000 metric tons, a quantitative analysis of carbon dioxide emissions is not warranted. The FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and, therefore, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Only extremely small amounts, if any, of the FCS 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, and to have 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

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. The FCS is a high molecular

³ The expected market volume is provided in a confidential attachment to this Environmental Assessment. *See Annex 1- Confidential Environmental Information.*

⁴ *See the Council of Environmental Quality "Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impact" available at <https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance>.*

weight polymer and does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

The products of complete combustion of the FCS are carbon dioxide and water. As indicated above, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Thus, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

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. No significant quantities of the FCS will be added to these water systems upon the proper incineration of the FCS, nor upon its use due to the very low production volume of the FCS and the lack of any significant introduction of substances into the environment, as discussed in Section 6 above.

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 FCS and its proper disposal. Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact materials containing the FCS are disposed. Furthermore, the very low production of the FCS for use in food-contact applications precludes any substantial release to the environment of its components. 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.

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

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the 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 is intended to be used in packaging which will be used in place of similar polymer materials, such as low density polyethylene (LDPE), now on the market for use in food packaging applications.

The partial replacement of these types of materials by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its 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. Furthermore, a portion of the raw materials used to prepare the FCS are biobased and derived from renewable plant sources. Packaging materials produced using the subject FCS are not currently recovered for recycling to a significant extent, but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future 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 with the FCS. This is primarily due to the minute levels of leaching of potential migrants from finished articles fabricated with the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the close similarity of the subject FCS to the materials it is intended to replace. 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 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 environmental impact. In view of the fact that the FCS constituents are not expected to enter the environment in more than minute quantities upon the 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 FCS as described herein is environmentally safe in every respect.

12. List of Preparers

- 1) Pamela L. Langhorn, J.D., Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001; 17 years' experience counseling and representing corporate entities on Food Additive Petitions and Food Contact Notifications, and assisting in the preparation of same, including Environmental Assessments when required.
- 2) William W. Reichert, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001; 9 years' experience evaluating and preparing Food Contact Notifications, including Environmental Assessments.

13. Certification

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



Pamela L. Langhorn
Counsel for PTT MCC Biochem Company Limited

February 3, 2016

Date

14. References

The following footnotes are found within the Environmental Assessment document:

1. *Advancing Sustainable Materials Management: Facts and Figures 2013. Assessing Trends in Materials Generation, Recycling and Disposal in the United States*, EPA530-R-15-003, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), June 2015. According to this report, of the total of 254.1 million tons of municipal solid waste (MSW) generated in 2013, 52.8% generally was land disposed, 112.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As the FCS 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 packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: $12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.
2. *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied*

Nutrition, Food and Drug Administration, May 2006, at
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.

3. The expected market volume is provided in a confidential attachment to this Environmental Assessment. *See **Annex 1- Confidential Environmental Information***.
4. See the Council of Environmental Quality “Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impact” *available at*
<https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance>.