Part IV (Environmental Information); Section B (Environmental Assessment)

☒An EA is required and has been prepared under 21 CFR 25.40 and is attached.

Note: An EA is a public document and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

1. Date August 25, 2017

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, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, DC 20001
Telephone: (202) 434-4291
E-mail: langhorn@khlaw.com

4. Description of the Proposed Action

The action requested in this Food Contact Notification (FCN) is clearance for the food contact substance (FCS), poly(1,4-butylene glycol-co-succinic acid), cross-linked with malic acid, for use in the manufacture of food-contact articles intended to contact all foods, except alcoholic foods, under Conditions of Use B ("Boiling water sterilized") through H ("Frozen or refrigerated storage; ready-prepared foods intended to be reheated in container at time of use"). 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. 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]

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

The FCS that is the subject of this Notification is polybutylene succinate cross-linked with malic acid. The FCS is prepared by the reaction of 1,4-butanediol, succinic acid, and malic acid. The Notifier produces several grades of the FCS with varying molecular weight profiles.

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

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[1] *See* EPA's 2014 internet summary of "Advancing Sustainable Materials Management: Facts and Figures", November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. *See also* "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016 at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report

According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, 52.6% was land disposed, 12.8% was combusted, and 34.6% 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 approximately 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% 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.

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 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. 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.

As secondary support that disposal of the FCS will not significantly impact the environment, we compared the market volume information for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (258 million tons of MSW in 2014), and have concluded that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there to be any extraordinary circumstances that would otherwise suggest a significant environmental impact resulting from post-consumer disposal of food-contact articles that contain the FCS. 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 EPA has indicated to be 33.1 million tons, as of 2014.[3]

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by EPA under 40 C.F.R. § 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

[3] *See supra*, note 1.

emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to Council on Environmental Quality (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." MSW combustion GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Incineration of food-contact articles containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws) because the FCS contains elements commonly found in MSW, and the amount of the FCS combusted represents a marginal amount of combusted MSW, as shown in the Confidential Attachment to the EA.

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 weight polymer and does not readily volatilize as evidenced by confidential molecular weight and thermogravimetric profile data cited in the EA's Confidential Attachment. 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 MSW currently combusted. Thus, the FCS will not significantly alter the emissions from properly operating MSW combustors, and incineration of the FCS will not cause MSW 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. EPA's regulations at 40 C.F.R. Part 258 require MSW owners to operate their facilities to prevent leaching from sanitary landfills. 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 significant environmental impact.

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; 18 years of 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. Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001; 1 year of 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.

[redacted]

Pamela L. Langhorn

August 25, 2017
Date

Counsel for PTT MCC Biochem Company Limited

14. References

The following footnotes are found within the Environmental Assessment document:

1. Advancing Sustainable Materials Management: Facts and Figures, Materials and Waste Management in the Unites States Key Facts and Figures (internet summary), U.S. Environmental Protection Agency, November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures.

2. Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Land and Emergency Management (5306P), November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

3. *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.

15. List of Attachments

1. Confidential Attachment