Environmental Assessment

1. Date: July 1, 2022

2. Name of Notifier: Eastman Chemical Corporation

3. Address: All communications on this matter are to be sent to:

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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 a copolyester made from dimethyl terephthalate (DMT), ethylene glycol (EG), and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD), intended for use in the manufacture of food-contact articles, which will then be used in contact with all foods, under conditions of use B - H, as described in Table 2[1].

The subject FCS is a co-polyester with the intended use as a basic resin in the fabrication of food-contact articles in single-use applications, such as condiment trays used in fast food restaurants, take-away single-serve yogurt cups and individual butter cups used in restaurants and in repeat-use food-contact articles, in contact with all types of food, at temperatures up to 100 °C.

The Notifier does not intend to produce finished food contact materials containing this FCS; rather it will sell the FCS to manufacturers that are engaged in the production of food contact articles. Food contact articles produced with the FCS will be utilized in 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 material being land disposed, combusted, composted, or recycled. According to the U. S. Environmental Agency's (US EPA) Advancing Sustainable Materials Management: Facts and Figures 2018, 50.0% of municipal solid waste generally was land disposed, 11.8% was combusted, and 23.6% was recovered for recycling and 8.5% was composted.[2] Assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.9% of the materials will be deposited in land disposal sites and about 19.1% will be combusted.[3]

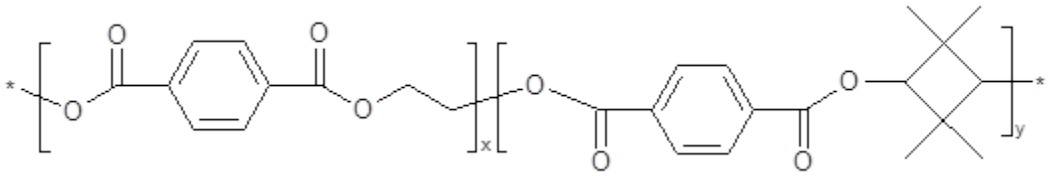
[1] https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm

[2] US EPA Report: Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States. December 2020.
https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

[3] The distribution of disposal may be re-calculated based on only the land disposal and combustion percentages from the EPA report as follows. % Combusted = 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted.
% Land disposed = 50.0% land disposed ÷ (11.8% combusted + 50.0% land disposed) = 80.9% land disposed.

5. Identification of the Subject of the Proposed Action

The subject of this notification is a polyester made from dimethyl terephthalate (DMT), 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD), and ethylene glycol (EG).



6. Introduction of Substances into the Environment

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 significant adverse environmental impact as a result of the manufacture of FCS. 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 significant environmental release is expected based on the use of the subject FCS as a component of food-contact materials. In these applications, the FCS 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 containing the FCS will be by conventional trash disposal and primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen and oxygen. Thus, the combustion products of the FCS may include carbon dioxide, which is a greenhouse gas (GHG). The carbon content of the FCS has been calculated, based on the chemical composition (available in the confidential attachment to the EA).

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 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.

EPA regulations require all 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 ground-water monitoring systems (40 CFR Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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 not expected to volatilize from food-contact articles. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured containing the FCS.

The FCS will make up a very small portion of the municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 CFR Pat 60 compliant operating municipal solid waste combustors to threaten a violation of applicable emission 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 any substances will be added to these water systems, so the fate of the FCS in the aqueous environment does not need to be addressed.

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 FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the FCS as a result of the proposed use of the FCS.

Herein, we respectfully state that there is no expectation of the FCS being introduced into 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 containing the FCS 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 the FCS-containing food-contact articles. The use and disposal of the FCS 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.

9. Use of Resource and Energy

The notified use of the FCS will not require additional energy or resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar polyester polymers already on the market. The manufacture of the FCS and use of the FCS in the food-contact applications will consume comparable amounts of energy and resources as similar currently marketed products. The raw materials used in the production of the FCS are commercially manufactured chemicals that are produced for use in various chemical reactions and production purposes. Therefore, the partial replacement of these materials by and their use

in food-contact applications with the subject FCS is not expected to have a significant impact adverse impact on the use of energy and resources.

Food-contact materials which are produced using 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 significant impact on current or future recycling programs.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles made containing the FCS, therefore, the FCS is not expected to result in environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

As no potential significant 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 FCS would otherwise replace, resulting in no significant environmental impact.

12. List of Preparers

Naeem Mady, M.Sc.

VP of Regulatory Market Access, *Food Contact and Regulatory Services,* Intertek Health, Environmental and Regulatory Services. With an educational background in Chemistry, Naeem has over 30 years of experience in chemical, health and regulatory consulting.

13. Certification

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

Date: July 1, 2022

Naeem Mady

VP, Regulatory Market Access
Health, Environmental & Regulatory Services
Intertek

14. References

US EPA Report: Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States. December 2020.

15. Attachments

Attachment 4 - Confidential Attachment to the Environmental Assessment.