

**ENVIRONMENTAL ASSESSMENT
FOOD CONTACT NOTIFICATION**

1. **Date:** October 21, 2022
2. **Name of Applicant:** Eastman Chemical Company
3. **Address:** Eastman Chemical Company
P.O. Box 511, B-54D
Kingsport, Tennessee 37662

All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), copolyesters of terephthalic acid with ethylene glycol, 1,4-cyclohexanedimethanol, diethylene glycol, and neopentyl glycol. The clearance established by this Notification would permit the use of the FCS in contact with aqueous, acidic, low-alcohol, and fatty foods under Conditions of Use C (“Hot filled or pasteurized above 150°F”) through G (“Frozen storage (no thermal treatment in the container)”).¹ Similar copolyesters are currently cleared under various food additive regulations and Food Contact Notifications, *e.g.*, 21 C.F.R. § 177.1315 (“Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers”), FCN Nos. 2066, 1234, 937, 280, and 179. The material made by the notifier would be a competitive replacement for the copolyesters currently marketed in the US.

The Notifier does not intend to produce finished food packaging from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste

¹ FDA’s Food Types and Conditions of Use are defined in Tables 1 and 2 at <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

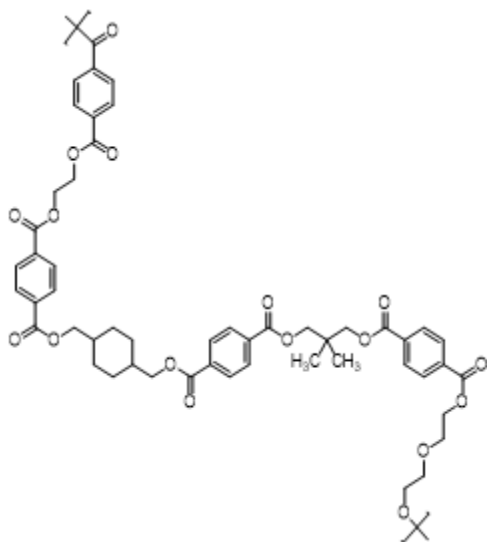
generally.² According to the U.S. Environmental Protection Agency's 2020 update regarding municipal solid waste in the United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.³ As the FCS is expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.⁴

5. Identification of Substance that is the Subject of the Proposed Action

Chemical Abstracts Service (CAS) name: Copolyester of terephthalic acid with ethylene glycol, 1,4-cyclohexanedimethanol, diethylene glycol, and neopentyl glycol.

CAS Registry Number: 208755-39-9

Structural Formula:



² *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed August 2022, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

³ *Id.*

⁴ 11.8% Combusted ÷ (11.8 % combusted + 23.6 % recycled + 50% land disposed) = 13.8% combusted.

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 materials. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used as the basic polymer to fabricate all forms of food-contact articles, will be entirely incorporated into the finished food-contact article, and is expected to remain with these materials throughout use of FCS in the food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal (*i.e.*, sanitary landfill or incineration) or recycling. The FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has been calculated. The concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications as the FCS would be incinerated in place of chemically related copolyesters already on the market.

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 C.F.R. 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 aquatic or terrestrial environment when disposed via landfill.

A confidential estimate of the total market volume anticipated for copolymers containing the FCS in food-contact applications in the United States is provided in a confidential attachment to this Food Contact Notification. Because the FCS will make up a very small portion of the total market for PET copolymers and, in turn, total MSW, we do not expect there to be any extraordinary circumstances, which otherwise would indicate a significant environmental impact, resulting from post-consumer disposal of articles that contain the FCS.

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. Because the FCS is a high

molecular weight polymer, the FCS does not readily volatilize. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from solid waste combustion facilities operating under 40 C.F.R. Part 60 as the FCS will likely be disposed in place of articles manufactured from compositionally identical polymers such as those cleared under FCN 85, 376, 635, 1064, and 1510. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the copolymers.

To assess the significance of these impacts, we considered the environmental impact analysis must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. Thus, according to 40 C.F.R. § 98.2(a)(3), stationary fuel combustion sources that emit 25,000 metric tons carbon dioxide (CO₂) equivalents (CO₂-e) or more per year must report their greenhouse gas (GHG) emissions to the EPA. Importantly, municipal solid waste combustion facilities are considered stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). Greenhouse gas emissions resulting from the use and disposal of the FCS result from the incineration of articles containing the FCS in municipal solid waste combustion facilities. Such facilities are regulated by the 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 emissions and sets an annual 25,000 metric tons carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

The carbon dioxide emissions expected from combustion of the FCS were estimated in the confidential attachment to the environmental assessment from the fifth-year confidential market projection. These predicted emissions are far below 25,000 metric tons annually. Thus, no significant environmental impacts are anticipated to result from combustion of the FCS in municipal solid waste combustion facilities, because the estimated GHG emissions are far below the threshold for mandatory reporting.

As indicated above in Item 6, the FCS will replace a portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food contact materials containing the FCS will not cause municipal solid 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. The fate of finished food-contact materials manufactured with the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

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 subject FCS. In particular, the polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental

conditions when these substances are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of 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 food-contact materials.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject 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 will replace use of other packaging materials.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Thus, there will be no impact on current 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 from the FCS. 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 significant 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 anticipated environmental impact.

12. List of Preparers

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications, Partner at Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001.

Kristin P. Wigglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Wigglesworth has over 5 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 16 years of total experience in FDA regulated industries.

13. Certification

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



Devon Wm. Hill
Counsel for Eastman Chemical
Date: October 21, 2022

14. List of References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, Accessed August 2022, at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>.

15. Attachments

1. Confidential Attachment - Attachment 14