# Environmental Assessment

**1. Date:** March 5, 2021

**2. Name of Applicant/Notifier:** DuPont Teijin Films Americas

**3. Address:**

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**4. Description of the Proposed Action:**

The action requested in this notification is to permit the use of a food-contact substance (FCS), polyethylene terephthalate-azelate (PET-Az) copolyester resin (CAS Reg. No. 25609-72-7), as a coating on polyethylene terephthalate (PET) films. The coated films will be used to make articles that are intended to hold food during storage and preparation for consumption. In these applications, the films will be used in contact with food under the conditions described in 21 C.F.R. § 177.1630, paragraphs (f), (g), and (h), including during oven cooking at temperatures above 250°F.

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2018, a total of 292 million tons of municipal solid waste (MSW) was generated in 2018. Of this amount, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered (a combination of waste recovered for recycling and for composting). The remaining 6.1% consists of food that was processed through other food management pathways.[1]

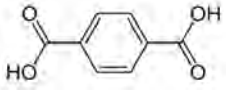
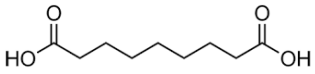
[1] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States.* November 2020. U.S. Environmental Protection Agency, Office of Land and Emergency Management. https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

Although PET films are capable of being recycled to yield feedstock for new polymeric materials, in practice there is little recycling of food-contact films in the United States. Therefore, our assessment of disposal of the FCS will assume the film is disposed of by either landfill or incineration. On this basis, we estimate that 19.1% of films containing the FCS will be combusted, and 80.9% will be land disposed.[2]

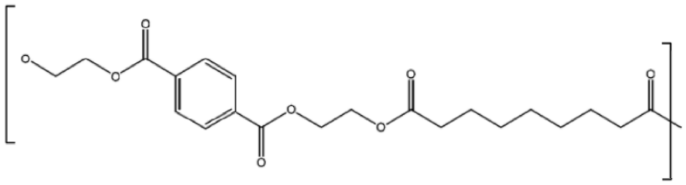
## 5. Identification of Substance that is the Subject of the Proposed Action

The food-contact substance that is the subject of this Notification is polyethylene terephthalate-azelate copolyester resin (CAS Reg. No. 25609-72-7). The FCS is composed of the elements carbon, hydrogen, and oxygen.

The subject resin is formed by the condensation polymerization of ethylene glycol with terephthalic acid and azelaic acid. The molecular structures of the starting monomers are as follows:

| | |
|---|---|
| Ethylene glycol |  |
| Terephthalic acid |  |
| Azelaic acid |  |

The polymerization process results in a copolyester resin with ethylene-terephthaloyl and ethylene-azeloyl groups in a random arrangement. The structure may be depicted generally as follows:



The chemical formula of the resin may be represented as $(C_9H_{16}O_4.C_8H_6O_4.C_2H_6O_2)_x$. The FCS is a polymer and is non-volatile.

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[2] Assuming the same ratio of combustion to landfilling as reflected in the 2017 EPA data, the fraction of films containing the FCS that are expected to be combusted is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. Likewise, the fraction of films expected to be land disposed = 50.0% ÷ (11.8% + 50.0%) = 80.9%.

## 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. Moreover, 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject FCS. In these applications, the FCS (*i.e.*, a polymer) is expected to remain with the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of the subject FCS will occur by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

As noted above, the FCS is composed of carbon, oxygen, and hydrogen, elements that are commonly found in municipal solid waste. Because of EPA's regulations governing landfills (40 C.F.R. Part 258) and the small quantities of the FCS that would be landfilled, only very small amounts of the FCS are expected to be introduced to land, and to an even lesser extent water. Similarly, because of the composition of the FCS and the small quantities of the FCS that would be combusted, it is not anticipated that combustion of the FCS would threaten a violation of EPA regulations governing municipal solid waste (MSW) combustion facilities (40 C.F.R. Part 60).

As secondary indication 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 MSW production (292 million tons MSW in 2018), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there is a significant environmental impact resulting from post-consumer disposal of 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 reported to be 34.6 million tons as of 2018.[3] Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and 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 and/or relevant state and local laws).

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

[3] *See* EPA, *Advancing Sustainable Materials Management: 2018 Fact Sheet, id.*

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 to GHG 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 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." In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws 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 below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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 particular, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when articles containing the FCS are disposed in sanitary landfills. Further, the low production volume of food-contact articles containing the FCS precludes any substantial release of its components to the environment. The absence of significant leaching is additionally assured by the regulations at 40 C.F.R. 258, which 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 ground-water 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. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The composition of the FCS is similar to other MSW incinerated at MSW combustion facilities, and the analysis in the confidential attachment to the EA confirms that the use of the

FCS as described in the Notification will not exceed the EPA GHGRP threshold of 25,000 metric tons.

**(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 subject polymer. The fate of 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. 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 polymer in contact with food. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

## 8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS.

## 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 subject FCS is not expected to result in a net increase in the use of energy and resources, because the FCS will be used in place of similar resins that are already on the market.

Manufacture of the FCS and its conversion to use in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of other, similar FCSs. Food-contact materials produced using the subject FCS are expected to be disposed of according

to the same patterns as other PET films. As noted above, there is little current recycling of PET food-contact film. Thus, there will be no significant 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 the subject FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

## 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

Cynthia B. Lieberman, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001; 13 years of experience performing evaluations relating to all aspects of Food Contact Notifications.

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001; over 35 years of experience preparing and performing evaluations relating to all aspects of Food Additive Petitions and Food Contact Notifications, including Environmental Assessments for such submissions.

## 13. Certification

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

Date: March 5, 2021

Cynthia B. Lieberman
Counsel for DuPont Teijin Films Americas

## 14. List of References

*Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States.* November 2020. U.S. Environmental Protection Agency, Office of Land and Emergency Management. https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

## 15. List of Attachments

Confidential Attachment