

ENVIRONMENTAL ASSESSMENT
UNITIKA LTD. FOOD CONTACT NOTIFICATION

1. **Date:** September 5, 2024
2. **Name of Applicant/Notifier:** Unitika Ltd.
3. **Address:** 31-3 Uji Hinojiri
Uji, Kyoto, 611-0021, Japan

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 permit the use of the Notifier's food contact substance (FCS), "polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified) prepared by the condensation of terephthalic acid with ethylene glycol and with one or more of the following: isophthalic acid and diethylene glycol. The finished polymer shall contain a total up to 13 mole-percent of total diethylene glycol and isophthalate units, with the diethylene glycol content expressed as mole-percent of the total glycol units and the isophthalate content expressed as mole-percent of total isophthalate/terephthalate units."

The FCS is intended for use as films with a maximum thickness of 50 µm intended for contact with aqueous, acidic, low-alcohol (up to 50% alcohol by volume), dry, and fatty foods under Conditions of Use A ("High temperature heat-sterilized (e.g., over 212 deg.F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use") as described in Table 2, and for use in contact with high-alcohol foods (greater than 50% alcohol by volume) under Conditions of Use E ("Room temperature filled and stored (no thermal treatment in the container)") through G ("Frozen storage (no thermal treatment in the container)") as described in Table 2. The known and desirable characteristics of PET food packaging can be modified by the addition of the isophthalate and diethylene glycol monomers. For example, the modifications may reduce the rate and degree of crystallization and melting point for improved processing. The finished food-contact film or articles must meet any applicable specifications, and are subject to all applicable conditions of use cited in title 21 C.F.R. 177.1630(f), (g), and/or (j). The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the Food Contact Notification (FCN).

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of plastics that will, in turn, be used to fabricate food-contact films. Food-contact materials produced with 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 (MSW) generally.¹ According to the U.S. Environmental Protection Agency's (EPA) update regarding MSW in the U.S., it is estimated that, of the 292,360,000 tons of MSW generated in 2018, 50.0% of MSW 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.² It is anticipated that disposal of the FCS polymers will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.

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

The FCS that is the subject of this Notification is a family of polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified) manufactured by the condensation of terephthalic acid with ethylene glycol and with one or more of the following: isophthalic acid and diethylene glycol. The FCS is intended for in finished polymers containing up to 13 mole percent of total diethylene glycol and isophthalate units. This family of polymers is generally referred to herein as PET copolyesters. The FCS is chemically identical to other PET copolyesters that are already cleared for the same uses covered by this notification under FCNs 85, 376, 635, 1064, 1510, and 2138.

FCS Monomers:

Terephthalic acid (CAS Reg. No. 100-21-0)
Isophthalic acid (CAS Reg. No. 121-91-5)
Ethylene glycol (CAS Reg. No. 107-21-1)
Diethylene glycol (CAS Reg. No. 111-46-6)

FCS CAS Name and CAS Reg. No.:

Multiple CAS names and CAS Reg. No. can be used to describe the PET copolyesters described in this FCN, depending on the exact monomers used. That Table is reproduced below for ease of reference.

¹ *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency (December 2020), available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

² *Id.*

Starting Monomers	CASRN	CAS Nomenclature; Chemical Formula
Terephthalic acid Ethylene glycol Diethylene glycol	25052-77-1	1,4-Benzenedicarboxylic acid, polymer with 1,2-ethanediol and 2,2'-oxybis[ethanol]; (C ₈ H ₆ O ₄ •C ₄ H ₁₀ O ₃ •C ₂ H ₆ O ₂) _x
Terephthalic acid Isophthalic acid Ethylene glycol	24938-04-3	1,3-Benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid and 1,2-ethanediol; (C ₈ H ₆ O ₄ •C ₈ H ₆ O ₄ •C ₂ H ₆ O ₂) _x
Terephthalic acid Isophthalic acid Ethylene glycol Diethylene glycol	27027-87-8	1,3-Benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,2-ethanediol, and 2,2'-oxybis[ethanol]; (C ₈ H ₆ O ₄ •C ₈ H ₆ O ₄ •C ₄ H ₁₀ O ₃ •C ₂ H ₆ O ₂) _x

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. The Notifier is aware of no information suggesting the existence of extraordinary circumstances³ 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 food-contact films, and will be entirely incorporated into the finished food-contact articles or films and is expected to remain with these materials throughout the use of the 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. The annual projected market volume of the FCS for food-contact use in the U.S. is provided in the Confidential Environmental Information attachment.

Disposal by the ultimate consumer of food-contact materials containing the FCS will be by recycling or conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes

³ Such extraordinary circumstances would include: (1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by federal, state, or local environmental agencies where the emissions may harm the environment; (2) the proposed action threatening a violation of federal, state, or local environmental laws or requirements; or (3) production associated with a proposed action that 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.

will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. ASTM standard number D7611 “Standard Practice for Coding Plastic Manufactured Articles for Resin Identification” provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.⁴ We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling.

The subject polymers consist of carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment, and an assessment of this worst-case release is also included in the same confidential appendix.

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. In this context, 40 C.F.R. § 98.2(a)(3) requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the EPA. Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Environmental Information attachment, 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. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, and oxygen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

⁴ ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

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 materials, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 C.F.R. Part 258)." 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 FCS 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 subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills.

C. Land

Due to 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 low production volume anticipated for the FCS in food-contact applications precludes any substantial release to the environment of its components. Thus, we have 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

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject FCS in landfills and by combustion are not anticipated as 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 food-contact articles and films containing the subject FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW 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. However, the use of the subject FCS in the fabrication of food-contact polymers is not expected to result in a net increase in the use of energy and resources because it is intended to be used as a replacement for compositionally identical polymers that are currently permitted under FCNs 85, 376, 635, 1064, 1510, and 2138.

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 the final conversion of the polymer to finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances.

Packaging materials containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. In general, we understand that the inclusion of increased levels of isophthalic acid, as well as diethylene glycol in PET is not expected to adversely affect recycling. Thus, where the subject polymers are used to fabricate food-contact articles, they will be replacement for articles currently being recovered for recycling and that are also covered by the indicated effective FCNs (FCNs 85, 376, 635, 1064, 1510, and 2138). In this way, there is no expectation of an impact on current or future recycling programs. In addition, as polymer resins are typically added to PET, use of the FCS in food-contact applications is not expected to have a negative impact on recyclability.

For the foregoing reasons, no adverse impacts on the use of natural resources and energy are expected as result of this Notification becoming effective.

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 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

Catherine R. Nielsen, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ms. Nielsen has a J.D., with over thirty years of experience drafting food additive petitions and FCN submissions and environmental assessments.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington DC 20001. Dr. Manning has over eight years of experience drafting FCN submissions and Environmental Assessments.

13. Certification

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

Date: September 5, 2024



Counsel for Unitika Ltd.

14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, *available at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>*.
2. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, November 2020.
Available at the following website:
https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.
3. 40 C.F.R. Part 258.
4. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

15. Appendices

1. Confidential Environmental Information.