

**ENVIRONMENTAL ASSESSMENT
M&G POLÍMEROS MÉXICO FOOD CONTACT NOTIFICATION**

- 1. Date:** March 11, 2021
- 2. Name of Applicant:** M&G Polímeros México, S.A. de C.V.
- 3. Address:** Petrocel Km. 2
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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), polyethylene terephthalate (PET) copolyesters that are diethylene glycol- and isophthalate-modified. The polymers will contain a total of not more than 10 mole-percent of diethylene glycol (DEG) and isophthalate (IP) units with the DEG content expressed as mole-percent of total glycol units and the IP content expressed as mole-percent of total (tere/iso)phthalate units. The clearance established by this Notification would permit the use of the FCS (PET copolyesters) in contact with aqueous, acidic, low-alcohol, and fatty foods under Conditions of Use A through H, and high-alcohol foods under Conditions of Use E through G. Equivalent PET copolyesters are currently cleared under FCNs 85, 376, 635, 1064, and 1510. The material made by the notifier would be a competitive replacement for the PET 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

generally.¹ According to the U.S. Environmental Protection Agency’s 2018 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.² 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.³

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), prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol and with one or more of the following: dimethyl isophthalate, isophthalic acid, and diethylene glycol. The finished polymer shall contain a total of not more than 10 mole-percent of diethylene glycol and isophthalate units, with the diethylene glycol content expressed as mole-percent of total glycol units and the isophthalate content expressed as mole-percent of total (tere/iso) phthalate 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, and 1510.

CAS Name and CAS Reg. No.: Consistent with FCN 85, Section A, Table A-1, 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 here for ease of reference.

Starting Monomers	CASRN	CAS Nomenclature; Chemical Formula
Dimethyl terephthalate Ethylene glycol Diethylene glycol	29154-49-2	1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,2-ethanediol and 2,2'-oxybis [ethanol]; (C ₁₀ H ₁₀ O ₄ •C ₂ H ₆ O ₂ •C ₄ H ₁₀ O ₃) _x
Terephthalic acid	25052-77-1	1,4-Benzenedicarboxylic acid, polymer with 1,2-

¹ *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed January 2021, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

Importantly, the PET industry has made significant commitments to achieving 100% recyclable plastic packaging within the next 5 – 10 years. *See* National Association for PET Container Resources (NAPCOR), *Brand Commitments*, Accessed December 2020, available at <https://napcor.com/why-pet/brand-commitments/>.

² *Id.*

³ 11.8% Combusted ÷ (11.8 % combusted + 23.6 % recycled + 50% land disposed) = 13.8% combusted.

Starting Monomers	CASRN	CAS Nomenclature; Chemical Formula
Ethylene glycol Diethylene glycol		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
Dimethyl terephthalate Dimethyl isophthalate Ethylene glycol	25135-73-3	1,3-Benzenedicarboxylic acid, dimethyl ester, polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol; (C ₁₀ H ₁₀ O ₄ •C ₁₀ H ₁₀ O ₄ •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
Dimethyl terephthalate Dimethyl isophthalate Ethylene glycol Diethylene glycol	57593-45-0	1,3-Benzenedicarboxylic acid, dimethyl ester, polymer with dimethyl 1,4-benzenedicarboxylate, 1,2-ethanediol, and 2,2'-oxybis[ethanol]; (C ₁₀ H ₁₀ O ₄ •C ₁₀ H ₁₀ O ₄ •C ₂ H ₆ O ₂ •C ₄ H ₁₀ O ₃) _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 materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); 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. 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, 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 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 National Association for PET Container Resources (NAPCOR) estimates that 28% of PET

bottles were recycled in 2019.⁴ As discussed in the EA for FCN No. 85, which covers an identical FCS, the inclusion of increased levels of diethylene glycol and isophthalate units in PET is not expected to adversely affect recycling and we do expect that the FCS will be recycled at a rate similar to traditional PET. 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.⁵ We therefore anticipate the articles manufactured with the FCS would be so marked and thus coded for recycling.

The FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. 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 compositionally identical copolyesters already on the market.

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 be disposed in place of compositionally identical polymers 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.

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

⁴ See National Association for PET Container Resources (NAPCOR), *NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow*, Accessed December 2020, available at <https://napcor.com/news/4970-2/>.

⁵ ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

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 compositionally identical polymers currently marketed in the U.S. based on existing clearances in FCNs 85, 376, 635, 1064, and 1510, and compositionally similar polymers cleared under 21 C.F.R. § 177.1630.

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 the compositionally identical polymers. 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. As discussed in the EA for FCN No. 85, the inclusion of increased levels of diethylene glycol and isophthalate units in PET is not expected to adversely affect recycling. The basis for this conclusion is set forth in Section 9 of the Environmental Assessment that was submitted in support of FCN No. 85. For the foregoing reasons, the Notifier respectfully submits that the proposed use of the FCS, copolyesters containing a total of up to 10 mole-% of DEG and IP units will have no significant adverse impact on current or future recycling programs for post-consumer PET.

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 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.

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 3 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 15 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 her knowledge.

Date: March 11, 2021



Catherine R. Nielsen
Counsel for M&G Polímeros México, S.A. de C.V.

14. List of References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, Accessed December 2020, at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>.

15. Attachments

1. Confidential Attachment – Attachment 13