

- 1. Date:** August 2, 2018
- 2. Name of Applicant:** Solvay Specialty Polymers
- 3. Address:** 4500 McGinnis Ferry Road
Alpharetta, Georgia 30005

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 Food Contact Notification (FCN) is to permit the use of poly(glycolic acid-co-isophthalic acid-co-trimethylolpropane) in food-contact applications:

- (1) in a multilayer structure where it will be separated from food by a layer of polyethylene terephthalate (PET) with a minimum thickness of 60 microns, and
- (2) at levels of up to 0.5% in blends with PET for direct contact with food.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance (FCS) that is the subject of this Notification will be sold to food-contact article manufacturers. Food-contact articles 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 subject resin will occur nationwide, with the material being land disposed, combusted or recycled in quantities similar to those reported for municipal solid waste generally.¹

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

The FCS that is the subject of this Notification is poly(glycolic acid-co-isophthalic acid-co-trimethylolpropane).

¹ *Advancing Sustainable Materials Management: Facts and Figures Report 2014*, U.S. Environmental Protection Agency, accessed February 2018, at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>. According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% generally was land-disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting).

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 resins containing the FCS. In these applications, the FCS is expected to 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 food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS resin is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable (*e.g.*, PET bottles), recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. We estimate that approximately 31% of PET bottles are recycled.² 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.³ The standard includes a designation for PETE+ "reserved for manufactured articles produced from Poly(ethylene terephthalate) that also contains at least one additional layer of a different material." Additionally, it includes an "OTHER" category "reserved for manufactured articles produced from any polymer chemistry not described by any other Code." Therefore, provided that good manufacturing practices are employed (properly labeling the final polymer composition of a final plastic article), contamination of the PET recycling stream can be prevented.

The FCS is composed of carbon, oxygen, and hydrogen. Thus, the combustion products of the FCS may include carbon dioxide. The carbon content of polymers manufactured with the FCS has been calculated based on the elemental composition of the FCS (available in the confidential attachment to the EA).

Greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion

² See <http://www.container-recycling.org/index.php/factsstatistics/plastic>. (1,798 million pounds recycled ÷ 5,764 million pounds total x 100% = 31% recycled).

³ ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2014. DOI:10.1520/D7611_D7611M-13.

facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. 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 ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to Council on Environmental Quality (CEQ) regulations under 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (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.

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 well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of polymers containing 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 light of the EPA regulations governing municipal solid waste landfills. EPA’s regulations 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 groundwater 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 collection 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. The FCS does not readily volatilize. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from municipal solid waste combustion facilities operating under 40 C.F.R. Part 60. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted, such polymers will not significantly alter the emissions from properly operating municipal solid waste combustors, and 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 substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact articles 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, hydrocarbon 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 very low 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 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 resins containing the FCS in the manufacture of articles intended for use 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 monomer 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 articles containing 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. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

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. The use of the subject polymer in the fabrication of food-contact materials is not expected to result in

a net increase in the use of energy and resources, because polymers manufactured with the FCS are intended to be used in food-contact articles in place of similar polymers already on the market in food-contact applications. Polymers currently used in the applications in which the FCS polymer is anticipated to be used include other polyglycolic acid polymers that are currently permitted under FCNs 574 and 958.

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, polymers containing 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.

In general, we understand that the FCS that is the subject of this Notification is intended for use as a component of PET beverage bottles. When the FCS is used to fabricate bottles, we expect them to be replacements for the bottles that currently contain polyglycolic acid covered by effective FCNs (FCNs 574 and 958).

For these reasons, no adverse impacts on the use of natural resources and energy are expected as a 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 using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the materials it is intended to replace. 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

George G. Misko, J.D., Partner, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Mr. Misko has over 30 years of experience drafting food additive petitions, FCN submissions, and environmental assessments.

Peter N. Coneski, Ph.D. in Chemistry, Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Dr. Coneski has 4 years of experience drafting food additive petitions, 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 his knowledge.

Date: August 2, 2018

George G. Misko


Counsel for Solvay Specialty Polymers

14. List of References

1. *Advancing Sustainable Materials Management: Facts and Figures Report 2014*, U.S. Environmental Protection Agency, accessed February 2018, at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>. According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% generally was land-disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting).
2. See *Container Recycling Institute's Plastics Facts & Statistics* at <http://www.container-recycling.org/index.php/factsstatistics/plastic>. (1,798 million pounds recycled ÷ 5,764 million pounds total x 100% = 31% recycled).
3. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2014. DOI:10.1520/D7611_D7611M-13.

15. Attachments

Confidential Attachment – Attachment 14