1. Date: May 1, 2020

2. Name of Applicant: SK Chemicals Co., Ltd.

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Seongnam-si, Gyeonggi-do, KOREA, 13494

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4. Description of the Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), copolymers of terephthalic acid (CAS Reg. No. 100-21-0), ethylene glycol (CAS Reg. No. 107-21-1), diethylene glycol (CAS Reg. No. 111-46-6), and 1,4-cyclohexanedimethanol (CAS Reg. No. 105-08-8), optionally branched with trimellitic anhydride (CAS Reg. No. 552-30-7) when used in food-contact materials. The FCS is intended for use in contact with aqueous, acidic, low-alcohol (up to 13% by volume alcohol), and fatty foods under Conditions of Use C through G, and in contact with high alcohol foods (up to 50% by volume alcohol) under Conditions of Use E through G.[1]

B. Need for Action

The FCS is intended to be used in the manufacture of single- and repeated-use food-contact articles.

C. Location of Use/Disposal

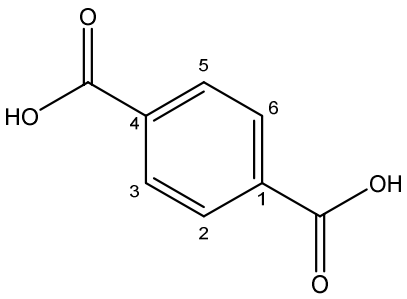
Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2017, approximately 52.1% of municipal solids waste is currently deposited in land disposal sites, 12.7% is combusted, and 35.2% is recovered (a combination of

[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.

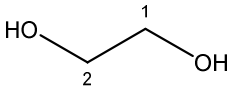
waste recovered for recycling and for composting).[2] The use of the FCS in food-contact materials will not impact the disposal patterns of the polymeric resins in which they are used.

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

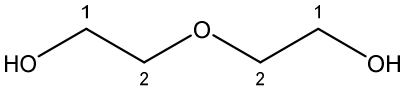
The FCS that is the subject of this Notification are copolymers of terephthalic acid (CAS Reg. No. 100-21-0), ethylene glycol (CAS Reg. No. 107-21-1), diethylene glycol (CAS Reg. No. 111-46-6), and 1,4-cyclohexanedimethanol (CAS Reg. No. 105-08-8), optionally branched with trimellitic anhydride (CAS Reg. No. 552-30-7). The FCS is a high molecular weight polymer. The polymer cannot be represented by a discrete chemical structure due to the presence of multiple monomeric repeating units. The chemical structures of the starting materials that may be used in the manufacture of the FCS are as follows:



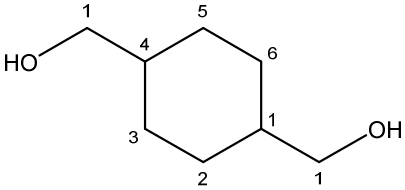
Terephthalic acid



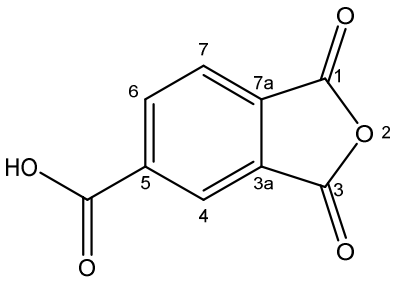
Ethylene glycol



Diethylene glycol



1,4-Cyclohexanedimethanol



Trimellitic anhydride

[2] *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to this report, of the total 268 million tons of municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted, and 35.2% 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 the FCS. 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, recycling processes 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.[3] 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.

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) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (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. 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 (CO_2-e) emission threshold for required reporting.

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[3] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. DOI:10.1520/D7611_D7611M-20.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulation (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

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. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, hydrogen, and phosphorus, 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).

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 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, 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 collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. As referenced in the Confidential Attachment, the FCS is a high molecular weight polymer and does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. 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. *See* Confidential Attachment for additional details.

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 concentration 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 nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when the food contact articles in which they are contained are disposed of. Furthermore, the very low production of the FCS for use in food-contact applications (as noted in the confidential attachment to the EA) 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 above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. None of these potential releases presents any toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *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 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 polyester polymers that are currently permitted under FCNs 937 and 1234.

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.

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

Jeffrey A. Keithline, J.D., Partner, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Keithline has over 20 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, N.W., Suite 500 West, Washington, DC 20001. Dr. Coneski has 6 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: May 1, 2020

Jeffrey A. Keithline

[redacted]

Counsel for SK Chemicals Co., Ltd

14. List of References

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.

2. *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to this report, of the total 268 million tons of municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted, and 35.2% was recovered (a combination of waste recovered for recycling and for composting).

3. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. DOI:10.1520/D7611_D7611M-20.

15. Attachments

Confidential Attachment – Attachment 14