Part IV – Environmental Impact of Food Contact Substance (21 CFR part 25)

B. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 CFR 25.40(a).

1. Date: September 25, 2020

2. Name of Notifier: SK Chemicals Co., Ltd**.**

3. Address: 310, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13494, Republic of Korea

4. Description of Proposed Action:

Intertek is pleased to submit this Environmental Assessment on behalf of SK Chemicals Co., Ltd. as an attachment to Food Contact Notification (FCN) for the Food Contact Substance (FCS), terephthalic acid polymer with 1,4:3,6-dianhydro-D-glucitol, 1,4-cyclohexanedimethanol and 1,2-ethanediol (Chemical Abstracts Service Registry Number (CASRN) 1038843-64-9), and optionally, prepared with trimellitic anhydride (TMA) (CASRN 552-30-7) as a branching agent. The FCS is marketed under the trade name ECOZEN Polymer with additives. The uses for this proposed FCS will replace FCNs 1075, 1444, and 1556.

This FCN seeks approval for use in articles or as components of articles that contact all food types under temperature conditions A through H. Thus, the action requested in this FCN is to permit the subject Notifier's ECOZEN polymer (CASRN: 1038843-64-9) for use in articles or as components of articles that contact food and beverages, including in repeat-use articles in contact with infant formula and human milk.

The FCS will be used for a number of end products, which, include, but are not limited to, bottles, hot-filled bottles, fatty food bottles, and alcoholic food bottles, utensils, food containers, cups, bowls, films, as well as infant bottles and cups for infant formula and human milk, and other food-contact articles. Because the Notifier is not the end-product manufacturer, the percent content of the FCS in final products cannot be entirely predicted.

5. Identification of substances that are the subject of the proposed action:

The FCS that is the subject of this FCN is ECOZEN Polymer with additives (CASRN: 1038843-64-9). The chemical name of the FCS is terephthalic acid polymer with 1,4:3,6-dianhydro-D-glucitol, 1,4-cyclohexanedimethanol and 1,2-ethanediol.

Manufacturing ECOZEN is a continuous process using the following monomers: terephthalic acid (TPA), ethylene glycol (EG), 1,4-cyclohexanedimethanol (CHDM), isosorbide, and trimellitic anhydride (TMA) as a branching agent. The physical properties of the produced ECOZEN Polymer is in the form of a colorless

(varies with product) solid pellet with a slight odor. The FCS has a molecular weight much greater than 10,000 Daltons, and it is considered a high molecular weight polymer.

ECOZEN is a thermoplastic modified polyethylene terephthalate (PET) polymer which is used in the manufacture of PET polymer finished articles. The ECOZEN polymer has desirable properties such as thermal stability and versatility. The FCS is differentiated by the inclusion of TMA, which increases the Heat Distortion Temperature (HDT) of a polymer resin. Raising the HDT of a polymer increases the temperature at which the material begins to soften under a fixed load[1].

6. Introduction of substances into the environment:

Given the known uses of ECOZEN and in various PET polymer materials and products, discussed in Section 4 above, we can expect the polymer to be used as a typical modified PET polymer product in the food container industry. Therefore, in the context of food contact products, the introduction of the FCS into the environment is expected to be as a PET polymer product at the end of life or disposal. This EA therefore, focuses on possible end-of-life pathways for the FCS as a PET product.

The Notifier is not a manufacturer of finished articles and does not intend to produce finished food-contact articles from the FCS. Rather, the FCS is produced by the Notifier as a component of varying finished polymeric materials that will be sold to manufacturers of finished food-contact articles. The FCS is manufactured in South Korea and SK Chemicals Co., Ltd. and customers in the USA will use the FCS in the production of packaging and food contact articles. Disposal and recycling of the FCS in food contact articles is anticipated in various jurisdictions across the USA in patterns corresponding to population and disposal, recycling, and combustion rates described below.

The United States Environmental Protection Agency (US EPA) releases facts, figures and trends in municipal solid waste, recycling, composting, combustion and landfilling across the USA[2]. The most recent, *Advancing Sustainable Materials Management: 2016 and 2017 Tables and Figures*, gives us perspective on the typical pathways for consumer polymer products disposal throughout the USA. Overall, of 267.8 million tons of municipal solid waste generated in the United States in 2017, 25.1% was recycled, 10.1% was composted, 52.1% was landfilled and 12.7% was combusted with energy recovery[3].

If we assume the worst-case scenario that food-contact articles containing the FCS are expected to be disposed of by land-filling or combustion (i.e., not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.6% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 12.7% combusted ÷ (12.7% combusted+ 52.1% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed. Greenhouse gas emission (GHG) calculations are presented in the confidential attachment.

Recycling: PET and PET variations are thermoplastic polymers, meaning they can be repeatedly softened and hardened. This characteristic makes thermoplastic polymers 100% recyclable[4]. Since ECOZEN is a

[1] Polymer Properties Database (2105). *Heat Distortion Temperature*. Available at [http://polymerdatabase.com/polymer%20physics/HeatDistortion.html]

[2] US EPA (2019) *Advancing Sustainable Materials Management: 2017 Tables and Figures.* Available at [https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf]

[3] US EPA (2019) *Advancing Sustainable Materials Management: 2017 Fact Sheet.* Available at [https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf]. Figure 2 (Page 3).

[4] RecycledPlastic.com (2014) *Polypropylene and Polystyrene*. Available at [http://www.recycledplastic.com/]

thermoplastic polymer, it is also recyclable and does not prevent food containers from being appropriately recycled through the municipal solid waste stream. Recycled PET can be used to produce various new products, such as textiles and clothing, housewares, automotive and industrial uses. Typically recycled plastics can only be down-cycled, however, PET bottles can often be recycled into bottles and other food-containers again[5].

That being said, plastics that include mixed resins may affect the quality and cost of recycling due to contamination from different types of resins in the recycling process[6]. There are several common methods for recycling PET, including in-plant recycling during the production process, mechanical recycling, chemical recycling and energy recovery from combustion[7].Among these, chemical recycling is an established process that facilitates the de-polymerization of the PET polymer chain back to its monomers or oligomers. This process allows virgin polymers to be produced for reuse in other products and contributes to PET's high recyclability rate[8]. PET products that are recycled by mechanical means involves separation of the polymers from contaminants and reprocessing into granules for reuse in other products. This method may lead to degradation of product properties and down-cycling to another product[9]. However, this down-cycling occurs as a result of contamination on the product, and not the addition of additives or co-polymers to the PET[10]. Given the high recyclability of PET products and the sophisticated recycling processes currently in practice, we anticipate no significant impact on recyclability of food contact articles that are produced with the FCS.

Combustion: The FCS consists of carbon, oxygen, and hydrogen as detailed in Section 5 above; elements that are normally found in municipal solid waste.

Complete combustion of hydrocarbons, such as the FCS, result in carbon dioxide (CO_2) and water. The FCS is not expected to cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (i.e., 40 C.F.R Part 60 and/or relevant state and local laws).

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) C02 equivalents (C02-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 CFR 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 municipal solid waste (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 (C02-e) emission threshold for required reporting.

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[5] RecycledPlastic.com (2014) What is Polyethylene Terephthalate (PET)? Available at [http://www.recycledplastic.com/]

[6] Nishijima, A, *et al*. *Life cycle assessment of integrated recycling schemes for plastic containers and packaging with consideration of resin composition*. J Mater Cycles Waste Management (2012) 14:52-64.

[7] Bartolome, L., et.al. Recent Developments in the Chemical Recycling of PET. Material Recycling – Trends and Perspectives (2012), ISBN: 978-953-51-0327-1, InTech. Available at [http://www.intechopen.com/books/materialrecycling-trends-and-perspectives/recent-developments-in-the-chemical-recycling-of-pet]

[8] Ibid.

[9] Ibid.

[10] Ibid.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 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." MSW combustion facilities are regulated by the EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG". Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-e emission threshold for required reporting. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown above, 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 to result from combustion of the FCS in MSW combustion facilities.

Landfill: No significant amounts, if any, of ECOZEN polymers are expected to enter the environment as a result of landfill disposal of food contact packaging materials manufactured with materials containing the FCS, in light of the Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills[11]. 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, to have groundwater monitoring systems and to take corrective action as appropriate.

Moreover, ECOZEN polymers are high molecular weight polymers (as detailed in Section 5) that contain no inorganic components or elements (i.e., metals), as detailed in the structural formula, which could leach out of the polymer under landfill conditions. A migration study conducted in accordance with the FDA guidance for Condition of Use C (Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations), FDA, 2007. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry) extracted polymer plaques manufactured with the FCS in ethanolic solutions over time. These extracts were analyzed for migration of the four monomer components (i.e., TPA, EG, CHDM and isosorbide) and the additive TMA. A table summarizing the findings of the migration study, as well as a reference to the study data are presented in the confidential attachment. CHDM, TMA and EG were detected in the migration analysis. TPA, and isosorbide were detected in extremely low concentrations as noted in the confidential attachment. When extracted under conditions which exaggerate environmental exposure conditions (e.g., with ten percent ethanol), only migration of TPA was detected. To put this migration into context, the component concentration in the tested extraction solution was determined and compared to the amount of the component present in the test plaque. These data and calculations are provided in the confidential attachment to this EA. In all instances, migration was a small percentage of the total amount of the component in the test plaque and the migrating concentration below 4.6 ppm. Considering that the migration conditions exaggerate environmental conditions and that any migrant would be further diluted in the waste stream, no significant exposure to the environment from TPA would be expected. If released into soil or water, TMA is expected to hydrolyze[12]. TPA is mobile in soils, but given modern landfill requirements as detailed previously within this section, this mobility is not expected to result in the migration of TPA beyond landfill boundaries. Furthermore,

[11] U.S. Environmental Protection Agency. *Criteria for Municipal Solid Waste Landfills.* 40 C.F.R. part 258

[12] Organisation for Economic Cooperation and Development (OECD), Screening Information Dataset (SIDS) Initial Assessment Report for 15th Initial Assessment Meeting (SIAM), Trimellitic Anhydride (TMA, CASRN 552-30-8) and Trimellitic Acid (TMLA, CASRN 529-44-9) (October 2002), available at: https://hpvchemicals.oecd.org/UI/handler.axd?id=be6d8c15-085e-4a6b-8ba0-46585019401d

TPA is not expected to volatilize, and has been found to be readily biodegradable.[13] Finally, isosorbide is a starch-based plasticizer and is known to be biodegradable and non-toxic.[14] Thus, in summary, these very small amounts of extractable components from the polymer are expected to readily biodegrade within landfill environments and are not anticipated to easily migrate outside a landfill.

Considering the foregoing discussion on recycling, combustion and landfill of the FCS, we respectfully submit that the use of the FCS would not create significant environmental impact via its inclusion in market-ready products.

Additionally, 21 C.F.R § 25.40(a) indicates that an environmental assessment ordinarily should focus on relevant environmental issues relating to its use and disposal from use, rather than the production and manufacture of food contact articles. No significant environmental releases are expected with the use of the subject FCS to fabricate food-contact materials at manufacturer locations. In these applications, the FCS will be entirely incorporated into the finished food contact articles. Any waste materials generated in this process, *e.g*. scraps, are expected to be disposed of as part of the manufacturer's non-hazardous solid waste in accordance with established procedures.

7. Fate of Emitted Substances in the Environment

Air: The polymers have high molecular weights and do not volatilize. Therefore, no significant quantities of any substances will be released into the air upon use and disposal via landfill of food packaging materials manufactured with ECOZEN Polymers. As detailed in Section 6, complete combustion of the FCS would result in carbon dioxide and water.

Additionally, the food-contact substance will make up a small portion of the total municipal solid waste currently combusted. Therefore, the food-contact substance will not significantly alter the emissions from 40 C.F.R. 60-compliant operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

As described above, articles manufactured with the FCS are expected to be either land-disposed or incinerated as municipal solid waste. These mechanisms of disposal are managed by local, state and federal regulations. Thus, no significant quantities of any substances will be released into atmospheric, terrestrial, or freshwater, estuarine or marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS.

Therefore, there is no expectation of any meaningful substance exposure to terrestrial or aquatic organisms as a result of the use and disposal of the FCS as notified.

8. Environmental Effects of Released Substances

As discussed in the sections above, the only substances expected to be released to the environment from the use and disposal of food packaging materials containing ECOZEN polymer consist of small quantities of

[13] Organisation for Economic Cooperation and Development (OECD), Screening Information Dataset (SIDS) Initial Assessment Report for 12th Initial Assessment Meeting (SIAM), Terephthalic Acid (TPA, CASRN 100-21-0) (June 2001), available at: https://hpvchemicals.oecd.org/ui/handler.axd?id=AF8877C9-8DFB-45E0-8188-492EBA68CDAE

[14] Battegazzore, D. et al. *Isosorbide, a green plasticizer for thermoplastic starch that does not retrograde*. Carbohydrate Polymers, 119, pp. 78-84.

combustion products and extractable compounds which are anticipated to readily biodegrade. The extractable components, are summarized in the confidential attachment. In addition, the polymer does not contain metals or other inorganics as shown by the chemical and structural formula presented in Section 5 which could be anticipated to leach from the polymer. Therefore, no significant impacts on organisms in the environment are expected as a result of the use and disposal of articles containing the FCS. In addition, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.,* 40 CFR Part 60 (regulation of solid waste combustors) and Part 258 (regulation of landfills).

9. Use of Resources and Energy

ECOZEN is comprised of carbon, hydrogen and oxygen atoms and like other currently approved polymers, similar to ECOZEN (see Section 4) is derived from resources such as petroleum and water, and inputs such as energy.

The effects of use and disposal of the FCS in food-contact articles was discussed in-depth in Section 6 of this environmental assessment. Studies discussed under the Recycling sub-section indicate that sophisticated chemical and mechanical recycling methods currently in practice for PET products results in a very high recyclability. High recyclability of all PET products, including those containing or made up of co-polymers, provide a promising alternative to raw material extraction for production of new finished articles. Although not quantifiable at this stage, we understand that the introduction of polymer blends into the market place that can be recycled into higher quality recycled polymers have the potential to reduce the burden of raw material extraction and fabrication. Thus, it is not anticipated that the production or fabrication of the FCS will have significant impact on resource use.

Manufacturers of food-contact containers and packaging utilize any number of polymers with the physical properties that suit their needs (e.g. transparency, durability, heat resistance, flexibility, etc.). To achieve the desired characteristics of the food-contact article, modified PET polymers such as ECOZEN are used to produce finished articles. In this case the FCS gives plastic products, such as PET, these desired characteristics, primarily to be used in place of other modifiers. For example, ECOZEN may be used with a PET product to enhance its thermal properties and may have been selected instead of glycol modifiers (to produce PETG). Because the FCS modifies PET in a manner that enhances the properties of food contact articles, we can also expect that it may be selected in place of other thermoplastic polymer products that may have higher burdens on the environment. Additionally, similar products are not new to the marketplace, as is demonstrated by other approved FCN's, such as FCN 1075 and 1444 discussed in Section 4 above. Thus, the replacement of currently used materials with the FCS is not expected to have significant environmental impact on the use of energy and resources. Manufacture of the FCS and its fabrication in food packaging articles will consume energy and resources in amounts comparable to the manufacture and use of materials currently used.

10. Mitigation Measures

As detailed in the sections above, no significant environmental impacts are anticipated. This is primarily due to the extremely low levels of leaching of potential migrants from the FCS, the insignificant impact on environmental concentrations of combustion products of the polymer, and the minor impacts on the recyclability of products made with the FCS. Thus, the FCS as proposed is not reasonably expected to result in any significant environmental impact that requires mitigation.

11. Alternatives to the Proposed Action

Discussions on the environmental effects of recycling, combustion, landfilling, resources use and energy demonstrate that the FCS is not expected to have any significant environmental impacts that would necessitate alternative actions to those proposed in this notification. Thus, the use and disposal of the FCS as is outlined in this Environmental Assessment will have no significant impacts on the environment. Further, the alternative of not approving the action notified herein would 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

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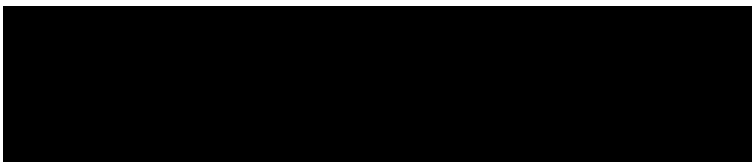
13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Sincerely,



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14. References:

Bartolome, L., et.al. Recent Developments in the Chemical Recycling of PET. Material Recycling – Trends and Perspectives (2012), ISBN: 978-953-51-0327-1, InTech. Available at [http://www.intechopen.com/books/materialrecycling-trends-and-perspectives/recent-developments-in-the-chemical-recycling-of-pet]

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U.S. Environmental Protection Agency. *Criteria for Municipal Solid Waste Landfills.* 40 C.F.R. part 258

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15. Confidential Appendix: Confidential Attachment