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:** November 17, 2017

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), below identified polymer. The FCS has Chemical Abstracts Service Registry Number (CASRN) 1632972-01-0. A search of the proposed FCS CASRN and alternative names for the substance, identifies several existing approved FCN's and their corresponding Environmental Assessments. This includes, but is not limited to:

- FCN 280: Terephthalic acid or dimethyl terephthalate with ethylene glycol and 1.4cyclohexanedimethanol that are modified by diethylene glycol co-monomer.

Similar to FCN 280, which is currently regulated in accordance with CFR 177.1315, this FCN seeks approval for use in articles or as components of articles that contact all food types under temperature conditions C through G. Thus, the action requested in this FCN is to permit the subject Notifier's polymer (CASRN: 1632972-01-0) for safe use in articles or as components of articles that contact food and beverages.

The FCS commercializes products that have an approximate molecular weight of [redacted] Daltons. According to the Notifier the FCS will be used for a number of end products intended for use as 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 identified by CASRN: 1632972-01-0. The chemical name of the FCS is 1,4-Benzenedicarboxylic acid, polymer with; 1,4-cyclohexanedimethanol,1,2-ethanediol, [4-(hydroxymethyl)cyclohexyl]methyl, 4-(hydroxymethyl)cyclohexanecarboxylate, 2,2'-oxybis[ethanol] and 4,4'-[oxybis(methylene)]bis[cyclohexanemethanol].

Manufacturing of the FCS is a continuous process using five monomers; terephthalic acid (TPA), ethylene glycol (EG), 1,4-cyclohexanedimethanol (CHDM), diethylene glycol (DEG), and a confidential monomer. The components of the confidential monomer are listed in the EA's Confidential Attachment.

The FCS is considered a high molecular weight polymer[1]. The specific molecular weights and monomeric composition by percent are provided in the confidential attachment to this EA.

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 polymer is produced outside of the United States. The FCS will be sold to manufacturers across the USA for inclusion in finished articles, including those that may come into contact with food.

The FCS is a thermoplastic co-polyester polymer to be used as a modifier for polyesters such as polyethylene terephthalate (PET). When combined with polyesters, the FCS polymer produces desirable properties such as; thermal stability, versatility and flexibility. The FCS is differentiated by the inclusion of the DEG and the prior mentioned confidential monomer which produces a co-polyester.

Before being used in food contact articles, the FCS polymer is typically fabricated with polyesters such as, PET that are common in the consumer marketplace and used to produce various food-contact articles. Thus, to the best of the Notifier's knowledge, the FCS polymer will primarily be used as a co-polyester with PET in production of articles that may come in to contact with food.

6. Introduction of substances into the environment:

We can expect the co-polyester to be used with typical polyester products in the food container industry, primarily PET. Therefore, in the context of food contact products, the introduction of the FCS into the environment is expected to be as a component of PET products at the end of life or disposal. This EA therefore, focuses on possible end-of-life pathways for the FCS combined with PET products.

The FCS is manufactured in production facilities located outside of the United States. SK Chemicals Co. and its customers in the USA will use the FCS in the production of packaging and food contact articles.

[1] U.S. Environmental Protection Agency. High Molecular Weight Polymers in the New Chemicals Program. Available at [https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new]

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[3]. The most recent, *Advancing Sustainable Materials Management: 2014 Tables and Figures*, gives us perspective on the typical pathways for consumer polymer products disposal throughout the USA. Overall, of 258 million tons of municipal solid waste generated in the United States in 2014, 25.7% was recycled, 8.9% was composted, 52.6% was landfilled and 12.8% was combusted with energy recovery[4]. More specifically within the subcategory "total plastics in containers and packaging," accounted for 14.3 million tons (5.5%) of total generated municipal solid waste in 2014. Of this amount, 2.39 million tons (16.7%) was combusted, 9.81 million tons (68.5%) was landfilled and 2.1 million tons (14.8%) was recycled[5]. However, as discussed in Section 5 above, the FCS is co-polyester used primarily in PET food packaging articles. Within the subcategory "plastic containers and packaging" and "other plastic packaging", PET specifically accounted for 3.87 million tons (1.5%) of total generated municipal solid waste in 2014. Of this amount 0.39 million tons (10.1%) was combusted, 2.51 million tons (64.8%) was landfilled and 0.97 million tons (25.1%) was recycled[6]. The US EPA table does not account for approximately 0.89 million tons of PET disposal in the subcategory "other plastic packaging", thus it was assumed to be landfilled.

Recycling: PET and PET variations are thermoplastic polymers, meaning they can be repeatedly softened and hardened. This characteristic makes thermoplastic polymers 100% recyclable[7]. Since the FCS is a thermoplastic additive to thermoplastic polymers, they are also recyclable and do 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[8].

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[9]. 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[10].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[11]. PET products that are recycled by

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3 US EPA (2016) *Advancing Sustainable Materials Management: 2014 Tables and Figures.* Available at [https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report]

4 Ibid. Table 35. Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling of Municipal Solid Waste, 1960 to 2014. 2014 data.

5 Ibid. Table 8 (page 13). Percent of total generated = 14.32 million tons (mt) ÷ 258.46 mt x 100 = 5.5%; Percent combusted = 2.39 mt ÷ 14.32 mt x 100 = 16.7%; Percent landfilled = 9.81 mt ÷ 14.32 mt x 100 = 68.5%

6 Ibid. Table 8 (page 13). Percent of total generated = 3.87 million tons (mt) ÷ 258.46 mt x 100 = 1.5%; Percent combusted = 0.39 mt ÷ 3.87 mt x 100 = 10.1%; Percent landfilled = 2.51 mt ÷ 3.87 mt x 100 = 64.8%

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

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

9 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.

10 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]

11 Ibid.

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[12]. However, this down-cycling occurs as a result of contamination on the product, and not the addition of additives or co-polyesters to the PET[13]. 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 manufactured with FCS.

Combustion: The FCS consists of carbon and hydrogen as detailed in Section 5 above; elements that are normally found in municipal solid waste. It should be noted that the substance does not contain chlorine, nitrogen, sulfur, metals, etc. as part of its chemical structure. Combustion of the FCS in isolation (i.e., not in combination with PET, etc.) is highly unlikely to occur in practice as the FCS is to be added to other polymer products.

Complete combustion of hydrocarbons, such as the FCS, result in carbon dioxide (CO_2) and water when there is enough oxygen to allow the fuel to completely react. In waste incinerators, it is unlikely that complete combustion will take place in all areas of the furnace and may produce very small amounts of incomplete combustion products. However, the FCS is not expectedto 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).

Besides CO_2 and nitrous oxide (N_2O), the FCS is not anticipated to produce other greenhouse gases (i.e., methane or fluorinated gases)[14] via waste incineration processes. Some N_2O production during waste incineration is inevitable due to the presence of atmospheric nitrogen; however, no nitrogen is present in the FCS and thus N_2O would not be generated during combustion due to the presence of nitrogen in the fuel source (i.e. the FCS).In addition, the EPA does not identify waste incineration as a major source of N_2O. Methane is not generated in waste incineration during normal operation, and only arises in particular and exceptional cases and to such a small extent that these emissions are not considered to be climate-relevant[15]. Finally, no halogens including chlorine or fluorine are present in the FCS which could result in the production of fluorinated gases during the combustion process.

Considering the worst case scenario that the FCS is not recycled and only landfilled or combusted, it has been determined through calculations (see confidential attachment) and the use of the US EPA Greenhouse Gas Equivalencies Calculator[16], that approximately only 3,934 metric tons of equivalent carbon dioxide (eCO_2) emissions would be produced as a result of combustion from incineration.

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

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12 Ibid.

13 Ibid.

14 U.S. Environmental Protection Agency. *Overview of Greenhouse Gases.* Available at [*www*.epa.gov/ghgemissions/overview-greenhouse-gases].

15 Johnke B, Hoppaus R, Lee E, Irving B, Martinsen T, and Mareckova K. Emissions from Waste Incineration. *Good Practise Guidance and Uncertainty Management in National Greenhouse Gas Inventories*.

16 US EPA (2016) Greenhouse Gas Equivalencies Calculator. Available at [https://www.epa.gov/energy/greenhouse-gasequivalencies-calculator]

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: According to the FCS safety data sheet (SDS), the product is not considered a hazardous waste as defined by the US Environmental Protection Agency (40 CFR 261).

No significant amounts, if any, of the FCS 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[17]. 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. 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.

Moreover, the FCS polymers are high molecular weight polymers that contains only minute levels of extractable materials even under conditions that greatly exaggerate environmental exposure conditions, as confirmed by the migration study testing conducted as part of this FCN. The results of the migration study are summarized below in Section 7.

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 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: 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 Polymers. 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 the FCS Polymers. As detailed in Section 6, complete combustion of the FCS would result in carbon dioxide and water.

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

Water: No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to ground or surface water systems through either the proper incineration of the FCS or through disposal of articles manufactured with the FCS in landfills.

Furthermore, as detailed in Section 6, EPA's regulations at 40 CFR 258 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. 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.

Land: 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 FCS Polymers. As noted above and supported by the migration study results provided in the EAs Confidential Attachment, the extremely low levels of maximum potential migration of components of the FCS indicate that virtually no leaching may be expected to occur under normal environmental conditions which finished food packaging materials are disposed. Therefore, there is no expectation of any meaningful exposure of terrestrial organisms to the FCS Polymers as a result of their proposed use in food contact articles.

8. Environmental Effects of Released Substances

As discussed in the sections above, and as detailed in the EA's Confidential Attachment, the only substances expected to be released to the environment from the use and disposal of food packaging materials containing FCS polymer consist of small quantities of combustion products and extractable compounds. 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

The FCS is comprised of carbon, hydrogen and oxygen atoms and like other currently approved polymers (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 co-polyesters, 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.

Furthermore, as discussed in Section 5, the FCS is differentiated by the inclusion of specific monomers, which produce a co-polyester with physical properties which are favorable to reducing energy consumption and costs associated with the manufacturing of finished articles.[18] This characteristic demonstrates that possible desired outcomes from use of the FCS are overall increased efficiency, energy reduction and cost savings during production.

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, modifiers such as the FCS are introduced with other polymers. 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, the FCS 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 is a modifier that enhances the properties of a food contact articles, we can also expect that it may be selected in place of other thermoplastic polyolefins products that may have higher burdens on the environment. Additionally, the FCS is not used to produce articles on its own and similar co-polymerization is not new to the marketplace, as is demonstrated by other approved FCN's, such as FCN 280 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 combined 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

The results of the migration study showed that the FCS polymer is not expected to migrate into food from food contact materials or into the environment through disposal pathways (i.e. land, water, air). Additionally, 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

Naeem Mady, M.Sc.

[18] Technical Effect Description (Confidential Attachment to the EA)

VP of Regulatory Services, *Food Contact and Regulatory Services,* Intertek Health, Environmental and Regulatory Services. With an educational background in Chemistry, Naeem has over 30 years of experience in chemical, health and regulatory consulting.

Sabrina Cescolini, P.Eng, M.Sc., LEED AP, WELL AP

Senior Associate - Sustainability, *Environmental, Safety and Sustainability Group*, Intertek Health, Environment and Regulatory Services. An Environmental Engineer with over 9 years of experience in environmental and sustainability consulting.

Kirsten Hoedlmoser, B.A.Sc., P.Eng., CHSC

Senior Associate – Environmental and Safety, *Environmental, Safety and Sustainability Group*, Intertek Health, Environment and Regulatory Services. A Chemical Engineer with over 6 years of experience in chemical and environmental engineering and health and safety consulting.

13. Certification

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

Sincerely,

[redacted]

Naeem Mady
VP, Regulatory Services
Intertek Regulatory Services

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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Johnke B, Hoppaus R, Lee E, Irving B, Martinsen T, and Mareckova K. Emissions from Waste Incineration. *Good Practise Guidance and Uncertainty Management in National Greenhouse Gas Inventories*.

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.

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

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

Technical Effect Description (Confidential Attachment to the EA)

U.S. Environmental Protection Agency. *High Molecular Weight Polymers in the New Chemicals Program.* Available at [https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new].

U.S. Environmental Protection Agency. *Overview of Greenhouse Gases.* Available at [*www*.epa.gov/ghgemissions/overview-greenhouse-gases].

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

U.S. Environmental Protection Agency (2016) *Greenhouse Gas Equivalencies Calculator*. Available at [https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator]

U.S. Environmental Protection Agency (2016) *Advancing Sustainable Materials Management: 2014 Fact Sheet Tables and Figures.* Available at [https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report]

Appended: Confidential Attachments