Part IV (Environmental Information), Section B (Environmental Assessment)

1. Date: May 30, 2024

2. Name of Applicant/Petitioner: Hyosung Chemical Corp.

3. Address: All communications on this matter are to be sent in care of Counsel for the Notifier:

George G. Misko, Counsel for Notifier
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001
Telephone: (202) 434-4170
Facsimile: (202) 434-4646
E-mail: misko@khlaw.com

4. Description of the Proposed Action:

The action identified in this FCN is to expand the authorized uses of the food-contact substance (FCS) carbon monoxide-ethylene-propylene terpolymer, also known as polyketone (CAS Reg. No. 88995-51-1) under effective FCN 1847, which became effective for Hyosung Corporation on May 13, 2018.[1] FCN 1847 notified FDA of Hyosung Chemical Corporation's intent to market the terpolymer for use as a component of (a) multilayer flexible packaging; (b) reheatable or microwavable rigid retort packaging; and (c) repeated use-food-contact articles, under Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use") and in contact with all foods except infant formula and human milk. The purpose of this FCN is to expand the use of the FCS to include use as a component of any food-contact article for which the subject polymer is technically suited, including single-use and repeated-use food-contact applications, as well as use under Condition of Use J ("Cooking at temperatures exceeding 250°F").

Polyketone polymers are relatively high molecular weight polymers having established utility as premium thermoplastics in the production of a variety of shaped articles, *e.g.*, containers for food and drink, by methods well known for the processing of thermoplastics such as extrusion, injection molding or thermoforming. Due to its high melting point (219 – 225°C), the FCS will find utility in packaging applications where olefin copolymers are not technically suited. Because the FCS will be used as a structural component of equipment and of food containers and

[1] *See* United States Food and Drug Administration, Inventory of Effective Food Contact Substance (FCS) Notifications: FCN No. 1847, *available at*: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=1847.

packaging materials, the minimum amount required to accomplish the intended technical effect may be as much as 100%.

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to converters engaged in the production of finished food-contact articles. Food-contact articles produced with the FCS will be used 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 polymer will occur nationwide, with the material being land disposed, combusted, or recycled. According to the United States Environmental Protection Agency's 2020 update of data regarding municipal solid waste in the United States, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered for recycling or composting.[2]

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

The FCS that is the subject of this notification is a high molecular weight carbon monoxide-ethylene-propylene terpolymer, also known as polyketone (CAS Reg. No. 88995-51-1). Polyketone has a molecular weight in the range of 130,000 to 400,000 daltons. Polyketone has an empirical formula of $(^{-}C{\equiv}O^{+})_x(H_2C{=}CH_2)_y(H_2C{=}CH_2\text{-}CH_3)_z$.

6. Introduction of Substances into the Environment:

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 [21 C.F.R. § 25.40(a)]. The Notifier is aware of no data or information suggesting that there may be any extraordinary circumstances in this case indicative of any adverse environmental impact resulting from manufacture of the polyketone terpolymers. Specifically, as set forth in FDA's guidance,[3] extraordinary circumstances include situations where (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment, (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)), and (3) production

---

[2] *See* United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

[3] *See* United States Food and Drug Administration, *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition* (May 2006), *available at*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan.

associated with a proposed action 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. No situations such as these apply to the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

No significant environmental release is expected upon the use of the subject terpolymer to fabricate food-contact materials. In these applications, the terpolymers are expected to be used as the basic polymer to fabricate all forms of food-contact articles and will be entirely incorporated into the finished articles. 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.

Finished food-contact articles produced from the polyketone terpolymers will be used nationwide. Therefore, food-contact articles produced from these terpolymers are expected to be disposed of in patterns similar to the current disposal of any other food-contact articles, *i.e.*, by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. We adjust the disposal pattern based on the quantities of MSW that are land disposed or combusted because the FCS is expected to be disposed primarily by landfill or combustion (*i.e.*, not recovered for recycling or composting). Therefore, about 80.9% of articles containing the FCS are expected to be land disposed with the remaining 19.1% incinerated.[4]

When food-contact articles made from the subject FCS are added to sanitary landfills, no significant amount of leaching of any substance from these materials into the environment is anticipated. Only extremely small amounts, if any, of the polymer constituents are expected to enter the environment due to the landfill disposal of food-contact articles in light of the Environmental Protection Agency's (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). The lack of a threat of any leaching of the subject FCS is further supported by the fact that the FCS is a high molecular weight polymer.

---

[4] *See* United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures*, *supra* footnote 2. Of the total 292 million tons of municipal solid waste (MSW) generated in 2018, 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered (a combination of waste recovered for recycling and for composting). 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 19.1% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

We have compared the market volume information for the FCS, detailed in **Attachment 5** ("Confidential Environmental Information"), to annual municipal solid waste (MSW) production (292 million tons total MSW in 2018),[5] and conclude that the FCS will make up a very small portion of the total MSW. Therefore, we do not expect there are any extraordinary circumstances, which otherwise would indicate a significant environmental impact, resulting from post-consumer disposal of articles containing the FCS in sanitary landfills.

The subject terpolymer consists only of carbon, hydrogen, and oxygen; elements that are commonly found in municipal solid waste. The proposed use of the FCS and the market volume data, available in a confidential attachment to the Environmental Assessment, show that (1) the FCS will make up a small portion of the total municipal solid waste currently combusted; (2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors; and, therefore, (3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

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 CFR Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG". Section 2 of this Part (40 CFR 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO_2 emission threshold for required reporting.

We refer to CEQ regulations at 40 CFR 1508.27 to evaluate the significance of the environmental impact of these GHG emissions. These CEQ regulations define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Title 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." GHG emissions from MSW combustion facilities are regulated under 40 CFR 98.2. 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. Therefore, no significant environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities.

Incineration of food-contact articles containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws) because the FCS contains elements commonly found in MSW, and the amount of the FCS combusted represents a marginal amount of combusted MSW, as shown in the Confidential Attachment to the EA.

---

[5] *See id.*

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 copolymers produced from the FCS. The FCS is a high molecular weight polymer and does not readily volatilize as evidenced by confidential molecular weight and thermogravimetric profile data cited in the Confidential Attachment to the EA. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the terpolymer.

(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 subject terpolymer. No significant quantities of the FCS will enter water systems upon the proper disposal in landfills as the FCS is a high molecular weight polymer and because of the regulations in place to control leaching from landfills (*i.e.*, as discussed under 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 due to the proposed use of the subject terpolymer. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances from the proposed use of the terpolymer.

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 articles intended for use in contact with food.

8. Environmental Effects of Released Substances:

No information is needed to address the environmental effects of substances released into the environment due to the use and disposal of the subject terpolymer 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 terpolymer 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. Parts 60 and 258.

9. Use of Resources and Energy:

The production, use, and disposal of the polyketone terpolymers involves the use of natural resources such as petroleum products, coal, and the like as is the case with other food contact articles. Polyketone terpolymers are intended to be used in place of similar materials now on the market for use in food-contact articles. Therefore, the use of the FCS is not expected to result in

a net increase in the use of energy and resources. Polymers currently used in such applications include, but are not limited to, polymers having good heat stability such as nylons and polyester copolymers.

The partial replacement of these types of materials by the subject polyketone terpolymers is not expected to adversely impact the use of energy and resources. Manufacture of the polyketone terpolymers, and their conversion to finished food-contact articles, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace.

10. Mitigation Measures:

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject terpolymer as explained above. Thus, the use of the FCS as proposed does not 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, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C., 20001. Mr. Misko has a J.D. and many years of experience with the preparation of FCN submissions and environmental assessments.

Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C., 20001. Dr. Hepp has a Ph.D. in Chemistry and many years of experience with the preparation of 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 30, 2024

George G. Misko
Counsel for Notifier

14. List of References:

1. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

2. United States Food and Drug Administration, *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition* (May 2006), *available at*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan.

15. List of Attachments:

Confidential Environmental Information