

Appendix 3
Revised Environmental Assessment

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

☒ An EA is required and has been prepared under 21 CFR 25.40 and is attached.

Note: An EA is a public document and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

1. **Date:** November 21, 2017
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4. Description of the Proposed Action

The action requested in this Food Contact Notification (FCN) is clearance for the food contact substance (FCS), carbon monoxide/ethylene/propylene terpolymer (polyketone). The FCS terpolymers are intended for use as a basic polymer component of multilayer, flexible packaging; as a component of reheatable or microwavable, rigid, retort packaging; and as a component of repeated use, food-contact articles. The FCS is intended for use 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")¹ and in contact with all foods, except infant formula and breast milk.

¹ Conditions of Use A through H are described in 21 C.F.R. § 176.170(c), Table 2, available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>.

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Polyketone polymers are relatively high molecular weight materials 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 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 resin will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2014 update regarding municipal solid waste in the United States, of the total of 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% was land disposed, 12.8% was combusted, and 34.6% 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 $(\text{C}\equiv\text{O}^+)_x(\text{H}_2\text{C}=\text{CH}_2)_y(\text{H}_2\text{C}=\text{CH}_2-\text{CH}_3)_z$.

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, the Notifier is not aware of data that suggests that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the polyketone terpolymers. Specifically,

² U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01 (November 2016), available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

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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 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. To the best of the knowledge of the Notifier, 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 packaging materials and films produced from the polyketone terpolymers will be used nationwide. Therefore, food-contact articles and films produced from these terpolymers are expected to be disposed of in patterns similar to the current disposal of any other food-contact articles and films, *i.e.*, by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. Because the FCS is expected to be disposed primarily by landfill or combustion (*i.e.*, not recovered for recycling or composting), we adjust the disposal pattern based on the quantities of MSW that are land disposed or combusted. Therefore, about 80.4% of articles containing the FCS are expected to be land disposed with the remaining 19.6% incinerated.⁴

³ FDA, *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 <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.

⁴ See EPA's 2014 internet summary of "Advancing Sustainable Materials Management: Facts and Figures," November 2016, available at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>; see also "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States," November 2016, available at

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When food packaging containers and films 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 as a result of 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). 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of a threat of any leaching of the subject FCS is supported by the fact that the FCS is a high molecular weight polymer.

We have compared the market volume information for the FCS, contained in a confidential attachment to the Environmental Assessment (Attachment 13 – Confidential Environmental Assessment),⁵ to annual municipal solid waste (MSW) production (258 million tons total MSW in 2014),⁶ 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.

With respect to disposal by combustion, the subject terpolymer consists 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

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<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, 52.6% was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed primarily 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 packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.6\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

⁵ See Attachment 13 to this FCN.

⁶ *Id.*

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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 CO₂-e emission threshold for required reporting.

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.” 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. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting 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.

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 EAs Confidential Attachment. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the terpolymer.

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(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 as a result of the proposed use of the subject terpolymer. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of 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 as a result of 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

As is the case with other food packaging materials, the production, use, and disposal of the polyketone terpolymers involves the use of natural resources such as petroleum products, coal, and the like. Because polyketone terpolymers are intended to be used in place of similar materials now on the market for use in food-contact articles, however, 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 have any adverse impact on the use of energy and resources. Manufacture of the polyketone terpolymers, and their conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace.

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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 from the subject terpolymer. 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


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13. Certification

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

Date: November 21, 2017


George G. Misko
Counsel for Hyosung Corporation

14. List of References

1. U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, (5306P) (November 2016), available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.
2. *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November

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2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

15. List of Attachments

1. Attachment 13 – Confidential Environmental Assessment