

ENVIRONMENTAL ASSESSMENT

GINPO PACK Co., LTD. FOOD CONTACT NOTIFICATION

1. **Date:** July 18, 2025 *
2. **Name of Applicant/Notifier:** GINPO PACK Co., Ltd.
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4. **Description of the Proposed Action**

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), polyisoprene grafted polypropylene and/or poly(propylene-co-ethylene). Specifically, the FCS will be used as a base polymer in the production of food contact articles. The FCS is intended to be used in both foamed and unfoamed food packaging applications at temperatures as severe as FDA's Condition of Use A through H as described in FDA Conditions of Use Tables 1 and 2. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in this FCN.

When used in foamed food packaging applications, the FCS provides insulation to the exterior of articles holding hot food, which allows for safer handling than with conventional polyolefin food packaging materials.

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food contact materials (FCM) containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste

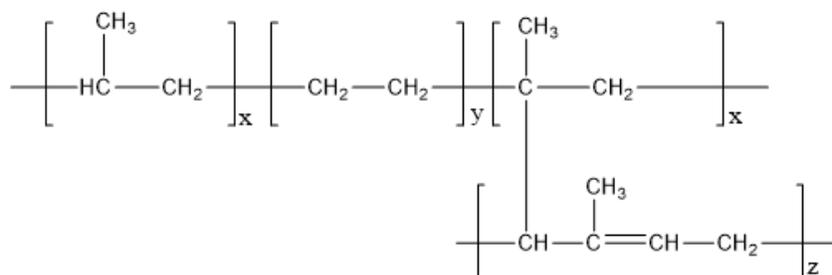
* Subsequent to this date, this EA was edited using the Adobe Acrobat direct edit tool to align the EA's description of the action with the notification regulatory language.

generally.¹ According to the U.S. Environmental Protection Agency's (EPA) update regarding MSW in the U.S., it is estimated that, of the 292.36 million tons of MSW generated in 2018, 50.0% of MSW was land disposed, 23.6% was recycled, 11.8 was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.² As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.³

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

The FCS that is the subject of this Notification is: polyisoprene grafted polypropylene and/or poly(propylene-co-ethylene). There is no specific CAS Registry Number for the FCS, but the monomers of the FCS are ethylene (CASRN 74-85-1), propylene (CASRN 115-07-1), and isoprene (CASRN 78-79-5). The repeat units are predominantly propylene.

The structure may be represented as follows:



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 food-contact materials. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from manufacture of the FCS. Such extraordinary

¹ *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, (December 2020). United States Environmental Protection Agency, Office of Land and Emergency Management (5306P), available at: [www.epa.gov/sites/default/files/2021-01/documents/2018 ff fact sheet dec 2020 fnl 508.pdf](http://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf)

² *Id.*

³ 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land disposed.

circumstances would include: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not included here.

No significant environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used as the basic polymer to fabricate food-contact articles and will be entirely incorporated into the finished food-contact articles and is expected to remain with these materials throughout the use of the FCS in food-contact applications and use/disposal by the consumer. 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 non-hazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS for food-contact use in the U.S. is provided in the Confidential Attachment to the Environmental Assessment.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact articles containing 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. We note that while articles produced with the FCS are inherently recyclable, the recycling infrastructure for such articles is currently under development. Therefore, as a conservatism, we have assumed that food-contact materials containing the FCS will be disposed of by conventional rubbish disposal.

The subject polymers consist solely of carbon and hydrogen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide from the FCS has been calculated in a confidential attachment to the Environmental Assessment, and an assessment of this worst-case release is also included in the same confidential appendix.

To evaluate the significant of the environmental impact of greenhouse gas (GHG) emissions, we considered whether they threaten a violation of Federal, State or local laws and requirements 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) of CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the 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.

Based on the anticipated market volume for the FCS, the expected carbon dioxide equivalent emissions, as shown in the Confidential Attachment to the Environmental

Assessment, are below 25,000 metric tons on an annual basis. Because the estimated GHG emissions fall 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 and hydrogen, 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 C.F.R. Part 258)." These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effect on the concentrations of and exposures to any of the substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

The FCS will make up a small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 CFR 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 as described in Section 6 of this EA.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills. Therefore, the fate of 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

Due to 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 FCS. In particular, the polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated low production volume anticipated for the FCS in food-contact applications precludes any substantial release to the environment of its components. Thus, we have no expectation of any meaningful exposure to terrestrial organisms of these substances resulting from 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 the subject FCS in the manufacture of food-contact materials. 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 of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject FCS in landfills and by combustion are not anticipated as 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 food-contact articles containing the subject FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources. However, the use of the subject FCS in the fabrication of food-contact polymers is not expected to result in a net increase in the use of energy and resources because it is intended to be used as a replacement for compositionally similar polymers.

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 FCM, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers with similar physical properties.

Packaging materials containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. As noted above, the recycling infrastructure for food-contact materials containing the FCS is currently under development. There is therefore no expectation of an impact on current recycling programs. As the FCS is largely comprised of polypropylene, there is similarly no expectation of an impact on future polyolefin recycling programs.

For the foregoing 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 from the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requirement mitigation measures of any kind.

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 anticipated environmental impact.

12. List of Preparers

Mark Thompson, Partner, Keller and Heckman LLP, 1001 G Street N.W., Suite 500 West, Washington, D.C. 20001. Mr. Thompson has a J.D. with over 15 years of experience drafting FCN submissions and environmental assessments.

Jason Schmidt, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street N.W., Suite 500 West, Washington, D.C. 20001. Dr. Schmidt has over 15 years of experience drafting 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: July 18, 2025



Mark Thompson
Counsel for Notifier

14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, available at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>
2. *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, (December 2020). United States Environmental Protection Agency, Office of Land and Emergency Management (5306P), available at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf
3. 40 C.F.R. Part 258.

15. Attachment

1. Confidential Attachment to the Environmental Assessment