

Environmental Assessment

- 1. Date:** December 13, 2021
- 2. Name of Notifier** ExxonMobil Chemical Company and its stewarded affiliates around the world (ExxonMobil Chemical)
- 3. Address:** All communications on this matter are to be sent to:
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4. Description of the Proposed Action:

The action requested in this notification is to permit the use of ethylene propylene copolymer in food packaging applications under expanded conditions of use. More specifically, the FCS in question and the intended food-contact use are described as follows:

ethylene propylene copolymer, CAS# 9010-79-1. The FCS is intended to be used as an article or component of an article used in contact with food. Both single and repeated uses are intended. The FCS may be used alone or with one or more other polymers for which an applicable food contact status exists. No thickness limitation is expected. The FCS will be in contact with all food types, under conditions of use C through G, as described in FDA 21 CFR 176.170, Table 1.¹ The FCS is not for use in contact with infant formula or breast milk. Such uses are not included as part of the intended use of the FCS.

The subject FCS offer several technical properties that make them useful in a variety of food-contact applications. In particular, the polymers impart improved clarity, flexibility, gas barrier properties, impact/puncture resistance, and improved heat seal performance to food packaging materials.

The FCS that are the subject of this notification are intended to be used as a substitute for other polyolefin copolymers and polypropylene homopolymers. These polymers are commonly used in thin films, where their improved balance of heat seal, toughness, and optical clarity properties are viewed as an advantage by customers. The polymers may also have utility in the production of molded articles; in these applications, the polymers are usually blended with other olefin polymers, such as Linear Low Density Polyethylene (LLDPE) and polypropylene (PP), to modify the flexibility, clarity, and low-temperature performance of the final food-contact article.

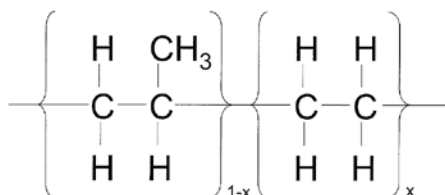
The Notifier does not intend itself to produce finished food-contact materials from the subject FCS. Rather, the FCS that are the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials and articles for use in contact with food. Food-contact materials produced with the FCS will be utilized in patterns

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

corresponding to the national population density and will be widely distributed across the country. According to the U.S. Environmental Protection Agency's (EPA) Advancing Sustainable Materials Management: Facts and Figures 2018, 50.0% of municipal solid waste generally was land disposed, 11.8% was combusted, and 23.6% was recovered for recycling and 8.5% was composted.² These figures may not reflect the pattern of disposal for food-contact materials containing the FCS, as these materials are not expected to be recycled to a significant extent. If the 32.1% recovered for recycling and composting is excluded, and all FCS-containing materials assumed to be land- disposed or combusted, it may be estimated that about 80.9% of the materials will be deposited in land disposal sites, and about 19.1% combusted.³

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

The food contact substances that are the subject of this Notification are ethylene propylene copolymer, (CAS Reg. No. 9010-79-1).



6. Introduction of Substances into the Environment

Under 21 CFR § 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, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject FCS to fabricate food-contact materials. In these applications, the FCS will be entirely incorporated into the finished food package. 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.

Disposal by the ultimate consumer of food-contact materials produced from the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject FCS consist of carbon and hydrogen, elements that are commonly

² US EPA Report: Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States. December 2020. https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

³ The distribution of disposal may be re-calculated based on only the land disposal and combustion percentages from the EPA report as follows. % Combusted = 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted.

% Land disposed = 50.0% land disposed ÷ (11.8% combusted + 50.0% land disposed) = 80.9% land disposed.

found in municipal solid waste. The products of complete combustion would be carbon dioxide and water. Based on the expected market volume for the proposed use of the FCS,⁴ the polymer will constitute an extremely small fraction of the total municipal solid waste currently combusted, which is estimated to be 11.8% of 292.36 million tons, or 34.5 million tons, as of 2017.⁵ Based on confidential market volume information for the FCS, we have calculated the expected carbon dioxide equivalent emissions associated with combustion of the FCS.

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. (*See* 40 CFR § 98.1, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.”) 40 CFR § 98.2 describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (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. In particular, 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.” As noted above, GHG emissions from MSW combustion facilities are regulated under 40 CFR § 98.2. Based on the confidential market volume information, 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.

The disposal of food-contact materials containing the FCS is not expected to significantly alter the emission from properly operating MSW combustors. Thus, incineration of the polymers will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations as set forth in 40 CFR Part 60 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’s 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 ground water monitoring systems (40 CFR Part 258).

7. Fate of Emitted Substances in the Environment

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 the atmospheric, terrestrial or freshwater, estuarine or marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS.

⁴ The expected market volume is provided in the Confidential Attachment 14 to the FCN.

⁵ See Footnote 1.

No significant effect on the concentrations of and exposures to any 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 packaging manufactured with this FCS.

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. Similarly, 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.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the environment due to the proposed use of the subject FCS in the manufacture of food-contact packaging intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject FCS consist of extremely small quantities of combustion products and leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and disposal of articles containing the FCS. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

The notified use of the FCS is not expected to result in a net increase in the use of energy and resources, since the copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications. Polymers currently used in the applications in which the FCS is anticipated to be used include olefin polymers that comply with the relevant specifications set forth in 21 CFR § 177.1520.

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 FCS. Thus, no mitigation is required.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the materials which the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

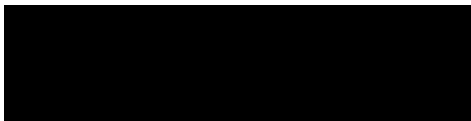
Naeem Mady, M.Sc.

VP of Regulatory Market Access, *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.

13. Certification

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

Date: December 13, 2021



Naeem Mady
VP, Regulatory Market Access
Health, Environmental & Regulatory Services
Intertek

14. References

US EPA Report: Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States. December 2020.

15. Attachment

Confidential Attachment to the Environmental Assessment: Estimate of Greenhouse Gas Emissions from Combustion.