

Environmental Assessment

- 1. Date:** April 5, 2023
- 2. Name of Notifier:** Exxon Mobil Corporation
- 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 copolymers in food packaging applications under expanded conditions of use. More specifically, the FCS in question and the intended food-contact uses are described as follows:

Ethylene-propylene copolymer, CAS# 9010-79-1. The FCS is intended to be used as an article or component of single and repeat-use articles in contact with food. 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 A through H, 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 offers several technical properties useful in a variety of food-contact applications. In particular, the polymers impart improved clarity, flexibility, impact/puncture resistance, and improved heat-seal performance to food packaging materials.

The FCS that is the subject of this notification is intended to be used as a substitute for other polyolefin copolymers and polypropylene homopolymers, particularly those regulated for use under 21 CFR 177.1520 (Olefin polymers) and those subject to prior effective FCNs.² These polymers contain up to 12 wt.% ethylene content, are produced using a proprietary metallocene catalyst system, and are commonly used in thin films. The subject copolymers offer several technical properties that make them useful in a variety of food packaging applications, including improved balance of heat-sealing, toughness, and optical clarity. The polymers may also have utility in the production of molded articles including blown film and thermoforming applications; the polymers are usually blended with other olefin polymers, such as linear low-density polyethylene (LLDPE) and polypropylene (PP) in these applications to modify the flexibility, clarity, and low-temperature performance of the final food-contact article. The polymers do not contain plasticizers, are recyclable, and may be burned without releasing

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

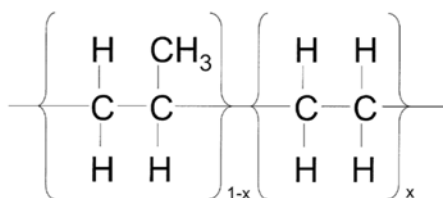
² Ethylene propylene copolymer (CAS Reg. No. 9010-79-1) is the subject FCS of FCNs 708, 832, 909, 936, 1086, 1350, 1538, 2199 and 2206.

dioxins.

The Notifier does not intend itself to produce finished food-contact materials from the subject FCS. Rather, the FCS that is 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 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.³ 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.⁴

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

The food contact substance that is the subject of this Notification is 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

³ 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

⁴ 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.

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 (*i.e.*, ethylene-propylene copolymer) is expected to be used as the basic polymer to fabricate all forms of food-contact articles and 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 by 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 consists of carbon and hydrogen, elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide and water. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that (1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 11.8% of 250.4 million tons in 2011),⁵ (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 under/or relevant state and local laws). Based on confidential market volume information for the FCS, we have calculated the expected carbon dioxide equivalent emissions associated with the 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 the 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.⁶ As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities.

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

⁵ The expected market volume is provided in the Confidential Attachment to the FCN. ⁶ Confidential Attachment

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 collection systems to prevent leachate from entering the ground and surface water and to have groundwater monitoring systems (40 CFR Part 258). The lack of any significant leaching is especially true considering that the subject FCS are of high molecular weight and contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

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

No significant effect on the concentrations of and exposures to any substances in the atmosphere is 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 the 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 freshwater, 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 consists 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 the 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 are 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

As is the case with other food packaging materials, the production, use, and disposal of the food-contact substance involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject food-contact substance in the fabrication of food-contact materials 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. Substances currently used in the applications in which the subject food-contact substance is anticipated to be used include those that are permitted in 21 CFR § 177.1520 and those food-contact materials produced from the effective Food Contact Notifications.

The partial replacement of these types of materials by the subject food-contact substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its conversion to finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances. Furthermore, the use proposed in this Notification for the subject food-contact substance, propylene-ethylene copolymer, is as a replacement for polyolefin polymers, *i.e.*, other propylene-ethylene copolymers. Food-contact materials produced using the subject food-contact substance are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

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 food-contact substance. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished articles employing the food-contact substance, the insignificant impact on environmental concentrations of combustion products of the food-contact substance, and the similarity of the subject food-contact substance to the materials it is intended to replace. Thus, the use of the food-contact substance as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that 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 that the subject food-contact substance would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Martin S. Hoagland, Ph.D..

Project Manager of Regulatory Market Access, *Food Contact and Regulatory Services*, Intertek Assuris. With an educational background in Biochemistry and Pharmacology/Toxicology, Martin has over 15 years of experience in regulatory review, compliance, and consulting.

13. Certification

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

Date: April 5, 2023



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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.