Environmental Assessment

1. Date: September 26, 2022

2. Name of Applicant/Notifier: NOVA Chemicals Corporation

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

Rachel A. Bond, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001
Telephone: (202) 434-4131
Facsimile: (202) 434-4646
E-mail: bond@khlaw.com

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), ethylene/octene copolymers containing up to 30 weight percent polymer units derived from 1-octene (CAS Reg. No. 26221-73-8). Such copolymers are described within the general class of linear low-density polyethylene (LLDPE) polymers. Specifically, the FCS will be used as articles or components of articles used in contact with all food types, under FDA's 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] The FCS is not intended for use in contact with infant formula and human milk. Although the specific end-use will be directed by the copolymer properties (*e.g.*, % octene content, density, etc.), the subject copolymers offer technical benefits such as impact modification, adhesion, and flexibility when used as lamination films, sealant layers, or other food-contact thermoplastic articles. Equivalent ethylene/octene copolymers are currently cleared under FCN 424 and various other related ethylene/octene copolymers are cleared under 21 C.F.R. § 177.1520 ("Olefin polymers").[2] The FCS will be a competitive replacement product for the existing ethylene/octene copolymers already on the market in the United States.

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

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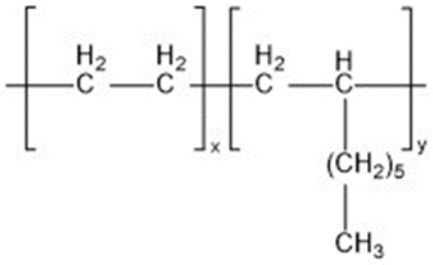
[1] FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

[2] Ethylene/octene copolymers are regulated under 21 C.F.R. §§ 177.1520(a)(3)(i)(4), 177.1520(a)(3)(i)(*a*)(1), and (a)(3)(i)(*e*), subject to compliance with applicable specifications and use limitations set forth in paragraph (c) of the regulation.

distributed across the country. Therefore, it is anticipated that disposal of food-contact materials 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 (MSW) generally.[3] According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of MSW is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[4] 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.[5]

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

The FCS that is the subject of this Notification is ethylene/octene copolymers containing up to 30 weight percent (wt.%) polymer units derived from 1-octene (CAS Reg. No. 26221-73-8). It is alternatively identified as "1-octene, polymer with ethene." The FCS is a high molecular weight saturated hydrocarbon copolymer, prepared by the random copolymerization of 1-octene and ethene monomers. It is composed of the elements carbon and hydrogen. The chemical structure of the FCS is shown below.



The polymer is composed of 70 – 100 wt.% ethene units ('x') and 0 – 30 wt.% octene units ('y').

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[3] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

[4] *Id.*

[5] By assuming that none of the FCS is recycled, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment (EA) 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[6] 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 materials containing the FCS. In these applications, the FCS is expected to be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain 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. ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.[7] We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling.

The FCS is a saturated polyolefin, composed of the elements carbon and hydrogen. Thus, the combustion products of the FCS may include carbon dioxide and water. The carbon content of the FCS (86% C) has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the confidential attachment to the EA) and is below 25,000 metric tons carbon

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[6] Such extraordinary 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 to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

[7] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

dioxide equivalent (CO2-e) emission per MSW combustor (MSWC) on an annual basis.[8] Thus, the concentrations of carbon dioxide in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications, as the FCS would be incinerated in place of compositionally identical LLDPE copolymers already on the market. Furthermore, to evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment (*i.e.*, 40 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 CFR 98, "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO2-e threshold for required reporting (40 CFR 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 CFR 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

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 CFR 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 food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

A confidential estimate of the total market volume anticipated for the FCS in food-contact applications in the United States is provided in a confidential attachment to this Notification. Because the FCS will make up a very small portion of the total market for LLDPE copolymers and, in turn, total MSW, we do not expect there to be any extraordinary circumstances, which otherwise would indicate a significant environmental impact, resulting from post-consumer disposal of articles that contain the FCS. The FCS will be a competitive replacement product for the existing ethylene/octene copolymers already on the market in the United States. Therefore, the FCS is substitutional for ethylene/octene copolymers already on the market and it presents no net increase in MSW or emissions.

[8] US estimated 75 MSWCs. *See* US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

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 FCS. Because the FCS is a high molecular weight polymer, the FCS does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in Item 6, the FCS will make up a very small portion of the total MSW currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations, as compared to the existing disposal of compositionally identical LLDPE polymers cleared under FCN 424 and FDA's food-contact regulations (*i.e.*, 21 C.F.R. § 177.1520). *See* confidential attachment to the EA for additional details.

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the 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 are anticipated as a result of the proposed use of the subject FCS. Thus, the fate of finished food-contact articles containing 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

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 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 production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment to the EA, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of 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.

8. Environmental Effects of Released Substances

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 polymer consist of 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/or 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/or disposal of 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 FCS involves the use of natural resources such as petroleum products, coal, and the like. The use of the subject polymer in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because the FCS is intended to be used in food-contact articles in place of similar polymers already on the market for use in food-contact applications. Polymers currently used in the applications in which the FCS polymer is anticipated to be used include competitive polyolefin films (*e.g.*, LLDPE polymers) already regulated by FDA under 21 C.F.R. 177.1520 ("Olefin polymers") and under the FCN program.

The partial replacement of this type of competitive material by the subject FCS is not expected to have any significant adverse impact on the use of energy and resources. Manufacture of the FCS, articles containing the FCS, and the final conversion of the polymer to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances.

For these reasons, no significant 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 using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive ethylene/octene resins). Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant 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 ethylene/octene

copolymers that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Manning has over six years of experience drafting FCN submissions and EAs.

Rachel A. Bond, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Bond has a J.D., with many 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: September 26, 2022

Rachel A. Bond
Counsel for NOVA Chemicals Corporation

14. References

1. FDA's Food Types and Conditions of Use for FCNs are set forth 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*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

3. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

4. US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), *see* https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

15. Attachment

1. Confidential Environmental Attachment – **Attachment 15**