Environmental Assessment

1. Date: April 29, 2025

2. Name of Notifier: Arkema, Inc.

3. Address:

Agent for Notifier:
Daniel C. Rubenstein, Partner
Steptoe LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of hexanedioic acid, polymer with azacyclotridecan-2-one and α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl), CASRN 70290-02-7 as a processing aid in olefin polymers, except for use in contact with infant formula and human milk. The Food Contact Substance (FCS) will be used as a polymer processing aid (PPA) at a level not to exceed 1,050 parts per million (ppm) by weight of olefin polymers in contact with all types of foods, under Conditions of Use A through H, as described in Tables 1 and 2.[1]

The Notifier does not intend to produce finished food-contact materials from the FCS. Rather, the FCS will be sold to manufacturers who produce food-contact materials. Those food-contact materials, in turn, will be utilized in patterns corresponding to the national population density and will be widely distributed across the United States of America. It is anticipated that disposal will occur nationwide, with material being land disposed, combusted, composted, or recycled, with about 80.9% of the materials being deposited in land disposal sites, and about 19.1% combusted.[2]

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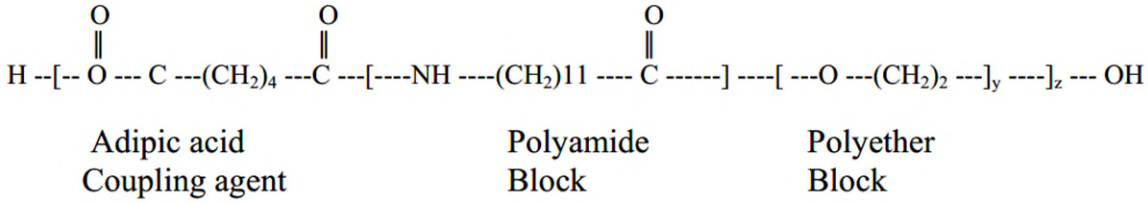
[1] *See* https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

[2] *See* U.S. Environmental Protection Agency's (EPA) "*Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States*" EPA530-F-20-009 (December 2020), *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

As noted in Table 1 of EPA's fact sheet, of the total 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% was land disposed, 11.8% was combusted, and 32.1% 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 19.1% of food-contact materials containing the FCS will be combusted annually. This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

5. Identification of the Subject of the Proposed Action

The subject of this notification is hexanedioic acid, polymer with azacyclotridecan-2-one and α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl), CASRN 70290-02-7. The structure may be represented as follows:



6. Introduction of Substances into the Environment

A. Resulting from manufacture of the FCS:

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. Current 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. Hence, information on the manufacturing site and compliance with relevant emission requirements is not provided in this Notification.

B. Resulting from use of the FCS:

No significant environmental release is expected based on the use of the subject FCS in food-contact materials. In these applications, the FCS will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process are expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

C. Resulting from disposal of the FCS:

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration.

Air (Combustion):

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. Considering the proposed use and use level of the FCS described under Section 4, it can be concluded that the FCS will make up an insignificant

portion of the plastic containers and packaging presented in the total municipal solid waste (MSW) currently combusted.

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, a GHG analysis was performed. This analysis is presented in the confidential attachment to the EA and is based upon the elemental composition of the FCS and assumes that 19.1% (described under Section 4) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the 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" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting at 40 CFR Part 98.2 of this regulation. From this analysis (contained in the confidential attachment to the EA), the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

As the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (*i.e.*, 40 CFR Parts 60 or 98), 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. As indicated above, the FCS will make up a small portion of the total MSW currently combusted. Thus, no significant adverse environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

Landfill:

Only extremely low levels, if any, of the FCS 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 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 food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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.

Water:

No significant effect on the concentrations of and exposure to any substances 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.

Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS,[3] to the annual plastic containers and packaging waste (14,530 thousand tons in 2018 from EPA), and concluded that the FCS and the food-contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste in the MSW. Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact on the aqueous environment resulting from postconsumer disposal of food-contact articles that contain the FCS due to the proposed use.

7. Fate of Emitted Substances in the Environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments.

Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental Effects of Released Substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released to the environment during use and disposal of food-contact articles containing the FCS.

Based on these considerations, no adverse effect on organisms in the environment, or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 CFR Parts 60 and 258.

[3] This comparison is contained in a confidential attachment.

9. Use of Resource and Energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials.
The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of other similar processing aids. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for similar processing aids.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of potential migrants from the finished article, the insignificant impact on environmental concentrations of combustion products, and the use of renewable resources involved in the manufacture of the FCS. Thus, the use of the FCS is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

As no potential significant adverse environmental effects are identified, it is therefore unnecessary to propose alternative actions to that proposed in the Notification. If the proposed action is not approved, manufacturers would simply continue the use of those materials which this FCS would otherwise replace, resulting in no significant environmental impact.

12. List of Preparers

Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, DC 20036, with over 14 years of experience with food-contact compliance matters, including FCN submissions and chemical registration submissions.

Daniel C. Rubenstein, Partner, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, DC 20036, with 15 years of experience with Food Additive Petitions, 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: April 29, 2025

Daniel C. Rubenstein, Partner

14. References

U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States,* (EPA530-F-20-009) December 2020. *Available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

15. Attachments

Confidential Attachment to the Environmental Assessment