Environmental Assessment

1. Date	October 14, 2020
2. Name of Applicant	USI Corporation
3. Address	Agent for Notifier: Joan Sylvain Baughan, Partner Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, D.C. 20036

4. Description of Proposed Action

The action requested in this notification is the establishment of a clearance for the use of styrene block copolymers with 1,3-butadiene, fully hydrogenated (CAS Reg. No. 66070-58-4) as the base polymer in the manufacture of food-contact articles intended for single and repeat use applications and contact with all types of food under Conditions of Use A through H, as defined at 21 CFR 176.170(c), Table 2.[1] The FCS is not for use in contact with infant formula and breast milk; such uses were not included as part of the intended use of the substance in the FCN.

The FCS provides technical properties that permit its use in the production of food-contact articles that require the clarity of general purpose polystyrene with the toughness of high impact polystyrene due to its thermal stability, UV durability, transparency, low water absorption, and low density.

The notifier does not intend to manufacture finished food-contact articles containing the FCS; rather, it will sell the FCS to compounders or to processors that are involved in the manufacture of food-contact articles. Food-contact articles produced with the food-contact substance 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 will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[2] Recycling of articles manufactured with the FCS is not anticipated.

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

[2] U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States* (November 2019), *available at:* https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to this report, 52.1% of municipal solid waste (MSW) generally was land disposed, 12.7% was combusted with energy recovery at permitted MSW combustion facilities, 10.1% was composted, and 25.1% was recovered for recycling. Assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.4% of the materials will be deposited in land disposal sites and about 19.6% will be combusted (12.7% combusted ÷ (12.7% combusted + 52.1% land disposed) = 19.6% combusted).

5. Identification of Substances that are Subject of the Proposed Action

The FCS that is the subject of this notification is styrene block copolymers with 1,3-butadiene, fully hydrogenated (CAS Reg. No. 66070-58-4).

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

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. 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.

The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgates 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action 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 provided here.

No significant environmental release is expected upon the use of the polymer used to fabricate packaging materials. In these applications, the FCS (i.e., a polymer) 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 nonhazardous waste in accordance with established procedures.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Disposal by the ultimate consumer of polymers employing the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill and incineration. The subject FCS consists of carbon and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

In accordance with 40 C.F.R. § 1508.27 the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context the greenhouse gas

(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. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting. Based on the proposed use of the FCS, the anticipated market volume, and calculations regarding the maximum introduced level of carbon dioxide equivalent as a combustion product, we have quantified the potential carbon dioxide and CO2 equivalent emissions resulting from combustion of the FCS.

The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis. Furthermore, we have concluded that the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, 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 Environmental Protection Agency's regulations governing municipal solid waste landfills.[3] EPA's regulations require new municipal 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, and to have ground water monitoring systems.[4] Although owners and operators of existing active MSW landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor ground water and to take corrective action as appropriate.

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 atmosphere or into freshwater, estuarine or marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS. Therefore, there is no expectation of any meaningful substance exposure to terrestrial or aquatic organisms as a result of the use and disposal of the FCS as notified.

8. Environmental Effects of Released Substances

As discussed previously, 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 FCS consist of extremely small quantities of combustion products, and leachate, if any. Thus, no

[3] 40 C.F.R. Part 258.
[4] Id.

significant adverse effects on organisms in the environment are expected as a result of the disposal of food contact articles made of 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 food additive are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy or resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace materials already on the market for this use. The manufacture of the FCS and use of the FCS in the food-contact applications will consume comparable amounts of energy and resources as similar currently marketed products. The raw materials used in the production of the FCS are commercially manufactured chemicals that are produced for use in various chemical reactions and production purposes. Therefore, the partial replacement of these materials by, and their use in food-contact applications with, the subject FCS is not expected to have any significant adverse impact on the use of energy and resources.

Food-contact materials produced using the subject FCS 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 articles made from the subject FCS; therefore, the FCS is not expected to result in environmental issues requiring mitigation measures.

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 approving the action proposed herein would simply result in the continued use of the materials that the FCS would otherwise replace, such as currently cleared styrene-based polymers; such action would have no significant environmental impact.

12. List of Preparers

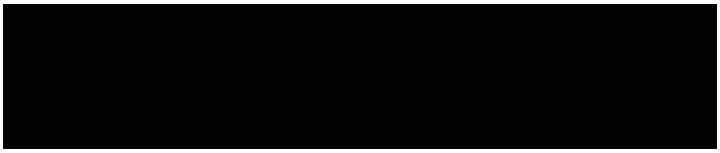
Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, D.C. 20036-1795. Ms. Kinne has over eight years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Avenue N.W., Washington, D.C. 20036-1795. J.D. with 29 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 her knowledge.

Date: October 14, 2020



Joan Sylvain Baughan, Partner

14. Attachments

Attachment 17 - Confidential Attachment to the Environmental Assessment