## Environmental Assessment

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| **1.** | **Date** | September 17, 2024 * |
| **2.** | **Name of Applicant** | LCY GRIT Corporation |
| **3.** | **Address** | Agent for Notifier: Daniel C. Rubenstein, Partner, Steptoe LLP<br>1330 Connecticut Avenue, N.W. 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 polymer with 1,3-butadiene, hydrogenated (the "food contact substance" or FCS, CAS Reg. No. 66070-58-4) for use in blends with other polymers 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 C.F.R. § 176.170(c), Table 2.[1] The FCS is not for use in contact with infant formula and human 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, oxidation resistance, creep resistance, and compression set.

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 80.9% of the materials being deposited in land disposal sites, and about 19.1% combusted.[2] Recycling of articles manufactured with the FCS is not anticipated.

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[1] *Available at:* 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 re-calculate 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.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several corrections to harmonize the EA to the final FCN regulatory language.

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

The FCS that is the subject of this notification is hydrogenated styrene-butadiene block copolymer (CAS Reg. No. 66070-58-4). The molecular weight range for the FCS polymer is approximately 47,000 to 300,000.

## 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.

No significant environmental release is expected upon the use of the polymer used to fabricate packaging materials. In these applications, the 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

### Resulting from Use of the FCS

Disposal by the ultimate consumer of polymers employing the subject FCS will be by conventional trash 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.

**Resulting from Disposal of the FCS**

**Land Disposal:** We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this environmental assessment, to the annual municipal solid waste (MSW) production (292 million tons MSW in 2018), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled.[3] Further, the proposed use of the FCS and corresponding market volume (available in the confidential attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which was estimated to be 11.8% of the 292 million tons of total MSW generated (or 34.5 million tons) in 2018. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant municipal solid waste combustion facilities, nor cause them to threaten a violation of applicable emissions laws and regulations (i.e., 40 C.F.R. Part 60 and/or other relevant state and local laws).

The FCS is composed of carbon, hydrogen, and oxygen, elements that are commonly found in municipal solid waste. EPA regulations require all 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 and Appendix 2). 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.

**Incineration**: As we anticipate incineration of articles containing the FCS, and because the FCS contains carbon and oxygen, we expect the release of carbon dioxide, a greenhouse gas (GHG).

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 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 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 consider whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

Based on the confidential market volume, the expected annual carbon dioxide equivalent emission, provided in a confidential attachment to the EA, is below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for

[3] *Ibid.*

mandatory reporting regulated under 40 C.F.R. Part 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 C.F.R. Part 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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

**B. Water**: No significant effects 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 subject FCS. No significant quantities of any substance will be added to these water systems upon proper incineration of the polymer, nor upon its disposal in landfills.

**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 FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of subject FCS.

Considering the foregoing, 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 articles intended for use in contact with food.

**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 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 potential 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 action would have no significant environmental impact.

**12. List of Preparers**

Patricia Kinne, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036-1795. Ms. Kinne has over 10 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, D.C. 20036-1795. J.D. with 14 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: September 17, 2024

Daniel C. Rubenstein, Partner

**14. Attachment**

Attachment 13 – Confidential Attachment to the Environmental Assessment