Environmental Assessment

1.	**Date:**	June 16, 2020
2.	**Name of Applicant/Petitioner:**	TSRC Corporation
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for Notifier: Mark Thompson, Partner Keller and Heckman LLP 1001 G Street, NW, Suite 500 West Washington, D.C. 20001 Telephone: 202-434-4252 E-mail: thompson@khlaw.com

4. Description of Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), styrene block polymers with 1,3-butadiene, hydrogenated (SEBS: CAS Reg. No. 66070-58-4), when used in food-contact materials. The FCS is intended for use in contact with food types III, IV-A, V, VII-A, and IX under Conditions of Use A through H.[1]

B. Need for Action

The FCS is intended to be used as a component of food-contact materials. The FCS is for use with other polymers to improve elasticity, clarity, impact and puncture resistance of articles in contact with food.

C. Location of Use/Disposal

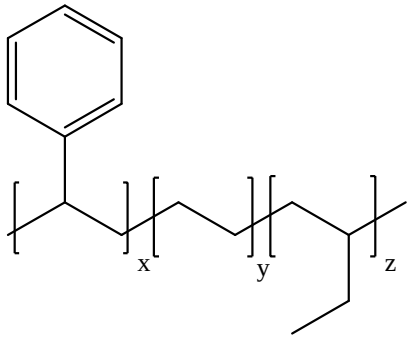
Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2017, approximately 52.1% of municipal solids waste is currently deposited in land disposal sites, 12.7% is combusted with energy recovery, 25.1% is recycled,

[1] FDA's Food Types and Conditions of Use are described on the Agency's website in Tables 1 and 2, *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

and 10.1% is composted.[2] The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the polymeric resins in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is styrene block polymers with 1,3-butadiene, hydrogenated (SEBS: CAS Reg. No. 66070-58-4). The FCS is a high molecular weight polymer. The polymer cannot be represented by a discrete chemical structure due to the presence of multiple monomeric repeating units. A generalized chemical structure of this substance may be represented as follows:



6. Introduction of Substances into the Environment

Under 21 C.F.R § 25.40(a) ("Environmental assessments"), 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 materials. The Notifier is not aware of any information to 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 subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS will be entirely incorporated into finished articles, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste material generated during the manufacture of the finished articles, *e.g.*, plant scraps, is expected to be disposed as part of the

---

[2] *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, 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, of the total 268 million tons of municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted with energy recovery, 25.1% is recycled, and 10.1% is composted.

finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The FCS is composed of carbon and hydrogen. Thus, the combustion products of the FCS include carbon dioxide. The carbon content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the EA).

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, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to EPA. Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that, when evaluating 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulation (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

Based on the confidential market volume, 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. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, and hydrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

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, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. As referenced in the Confidential Attachment, the FCS is a high molecular weight polymer and does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (as detailed in Item 6 of this EA). *See* Confidential Attachment for additional details.

B. Water

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. The fate of 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 concentration 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 nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when the food contact articles in which they are contained are disposed of. Furthermore, the very low production of the FCS for use in food-contact applications (as noted in the 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, the environmental fate does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and landfill leachates, if any. None of these potential releases presents any significant toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

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 manufacture of the FCS will consume comparable amounts of energy and resources as the manufacture of similar styrenic polymers that are already permitted for use in such applications, as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles with or without comparable additives. Because the FCS is used at a low level in the production of food-contact materials (as noted in the confidential attachment to the EA), there will be no significant 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 articles fabricated with the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished food-contact materials, and the insignificant impact on environment concentrations of combustion products of the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No significant adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace, such as comparable styrenic polymers permitted for such uses via other effective Food Contact Notifications. Such action would have no significant environmental impact.

12. List of Preparers

1. Mark Thompson, J.D., Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Mr. Thompson has over 10 years of experience drafting Food Additive Petitions, FCN submissions, and Environmental Assessments.

2. Peter Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Dr. Coneski has over 6 years of experience preparing FCN submissions, including their 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: June 16, 2020

Mark Thompson

Counsel for TSRC Corporation

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's food types and Conditions of Use are defined on the Agency's website in Tables 1 and 2, *available at* https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf.

15. Attachment

1. Confidential Attachment to Environmental Assessment.