

## Environmental Assessment

- Date:** August 14, 2024
- Name of Applicant:** Formosa Plastics Corporation
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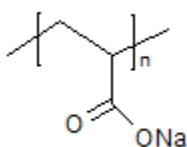
#### 4. Description of the Proposed Action

The action proposed in this Notification is to provide for the use the sodium salt of a cross-linked 2-propenoic acid homopolymer as a fluid-absorbent component of food packaging materials. The FCS is intended to be used in contact with poultry, red meat, fish and seafood, and fruits, and vegetables. Packages containing the FCS will be used under Conditions of Use E through G (Room temperature, refrigerated, and frozen; no thermal treatment in the package) as described in 21 CFR 176.170(c), Table 2.

The Notifier does not produce finished food-contact articles from the Food Contact Substance (FCS). Rather, the FCS that is the subject of this Notification will be sold to manufacturers who make absorbent pads for food packaging. Food packaging produced with the FCS will be used in patterns corresponding to the national population density and will be widely distributed throughout the country. Therefore, it is anticipated that disposal of such packaging will occur nationwide, with the food-contact article being land-disposed or combusted in proportions similar to those reported for municipal solid waste generally.

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

The FCS that is the subject of this Notification is a crosslinked polyacrylic acid, sodium salt (CAS Reg. No: 9003-04-7). The structure of the base polymer may be depicted as follows:



Chemical formula:  $[-\text{CH}_2-\text{CH}(\text{CO}_2\text{Na})-]_n$

## 6. Introduction of Substance into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal of, rather than the production of, FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances that indicate any adverse environmental impacts resulting from 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 FCS to manufacture absorbent pads. In these applications, the FCS is expected to be entirely incorporated into and remain with the finished food-contact article. Any waste material generated in this process, *e.g.*, plant scrap, is expected to be disposed of as part of the food-contact article manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of absorbent pads containing the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. Absorbent pads containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. According to the United States Environmental Protection Agency's 2020 update of data regarding municipal solid waste in the United States, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered for recycling or composting.<sup>1</sup> We recalculate the disposal pattern here based on only the quantities of MSW that are land disposed or combusted because the FCS is not recovered for recycling. We therefore estimate that approximately 19.1% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows:  $11.8\% \text{ combusted} \div (11.8\% \text{ combusted} + 50.0\% \text{ land disposed}) = 19.1\% \text{ combusted}$ . Therefore, it is anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

The FCS is composed of carbon, oxygen, hydrogen, and sodium; elements that are commonly found in municipal solid waste. 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. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of packaging that contains the FCS. Further, the proposed

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<sup>1</sup> See United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at: [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf).

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, estimated to be 11.8% of the 292 million tons total waste generated, or 34.5 million tons, as of 2018.<sup>2</sup> 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 absorbent pads containing the FCS will not cause municipal solid 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).

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<sub>2</sub> equivalents (CO<sub>2</sub>-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (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 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO<sub>2</sub>-e) emission threshold for required reporting.

We refer to CEQ regulations at 40 C.F.R. § 1508.27 to evaluate the significance of the environmental impact of these GHG emissions. These regulations define ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. Title 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.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the Environmental Assessment, 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.

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 EPA’s regulations

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<sup>2</sup> See United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at:

[https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf).

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).

## **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, as the FCS does not readily volatilize.

As indicated above in item 6, the FCS will make up a very small portion of the total MSW currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 CFR 60-compliant operating MSW combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations. See the Confidential Environmental Assessment for additional details.

### **b. Water**

No significant effects on the concentrations of, and exposures to, any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS polymer. No significant quantity of any substance will enter water systems upon the proper incineration of the polymer nor upon its disposal in landfills due to negligible levels of migration of polymer components. 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 concentrations of and exposure to any substances in terrestrial ecosystems are anticipated due to the proposed use of the subject FCS. The polymeric nature of the FCS is expected to result in virtually no leaching of the FCS components under normal environmental conditions when absorbent pads containing the FCS are disposed. Thus, there is no expectation of any meaningful exposure of polymer-borne substances to terrestrial organisms due to the proposed use of the FCS.

Considering the foregoing, 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 FCS in the manufacture of absorbent pads 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 subject polymer consist of extremely small quantities of combustion products and negligible levels of migrating polymer components. Thus, no adverse effect on organisms in the environment is

expected due to the disposal of absorbent pads containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment due to 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 absorbent pads containing the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulation in 40 CFR 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. However, use of the subject FCS in the fabrication of absorbent pads is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in absorbent pads that will be used in place of similar articles already on the market.

Manufacture of the FCS, and its conversion to use in an absorbent pad, will consume energy and resources in amounts comparable to the manufacture and use of other similar food-contact substances. Furthermore, the finished absorbent pad in which the FCS is used is not currently recovered for recycling. 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**

No significant adverse environmental impacts are expected to result from the use and disposal of absorbent pads containing the FCS. This is primarily due to the minute levels, if any, of leachable components of the FCS from the enclosed absorbent pad employing the FCS, and the insignificant impact on environmental concentrations of combustion products of the FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

## **11. Alternatives to the Proposed Action**

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in the Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the material that the subject FCS would otherwise replace; such action would have no significant environmental impact.

## **12. List of Preparers**

Cynthia B. Lieberman, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Juris Doctorate; many years of experience in preparing environmental assessments related to FCNs.

Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001. Ph.D. (Chemistry); many years of experience preparing environmental assessments related to FCNs.

### **13. Certification**

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.



Cynthia B. Lieberman, Partner  
Counsel for Formosa Plastics Corporation  
Date: August 14, 2024

### **14. List of References**

1. Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations, Appendix V, Table 2: Conditions of Use. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry>.

2. See United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), available at: [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf).

### **15. List of Attachments**

1. Confidential Environmental Assessment (Attachment 12)