

### Environmental Assessment

1. **Date:** March 31, 2020
2. **Name of Applicant/Notifier:** Harima Chemicals, Inc./Plasmine Technology, Inc.
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All communications on this matter are to be sent in care of the Counsel for the Notifier:

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4. **Description of the Proposed Action:**

**A. Requested Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), a copolymer of acrylamide, 2-methacryloxyethyltrimethyl ammonium chloride, itaconic acid, and N,N'-methylenebisacrylamide (no CAS Reg. No. has been assigned), when used as a wet and dry strength agent and retention and/or drainage aid added prior to the sheet forming process in the manufacture of paper and paperboard, and as a pitch control agent added prior to the sheet forming process/or to pulp in the pulping process immediately prior to sheet forming. The polymer is intended for use at a maximum level of 30 lbs/ton dry weight of the finished paper. The finished materials manufactured with the aid of the FCS are intended for use in contact with all foods, including with powdered infant formula (*i.e.*, excluding ready-to-consume infant formula and infant formula concentrate), under Condition of Use A ("High temperature heat-sterilized (e.g. over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in the container at time of use").<sup>1</sup>

**B. Need for Action**

The FCS is intended to be used as wet and dry strength agent, a retention and/or drainage aid, and a pitch control agent, in the manufacture of food-contact paper and paperboard. The FCS improves the tensile strength and internal bond strength of paper and paperboard, as well as aids in the retention and drainage properties of paper and paperboard articles.

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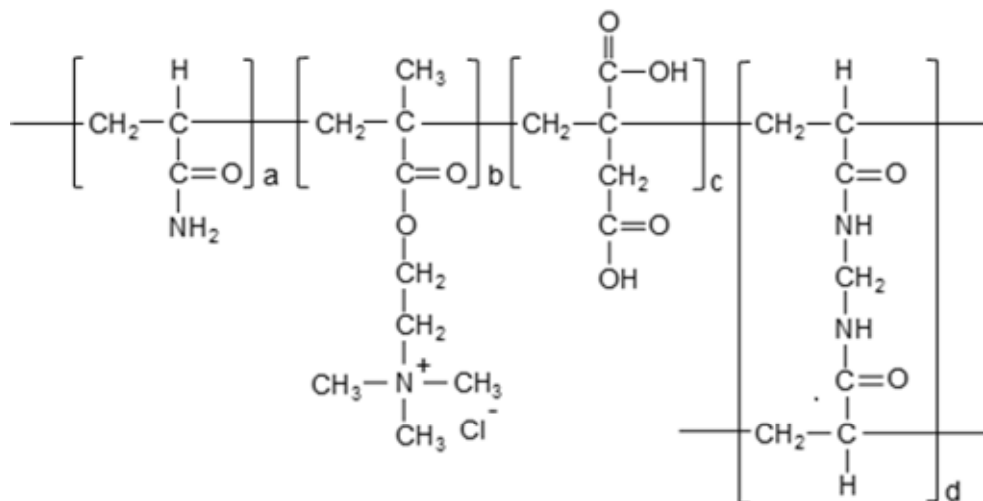
<sup>1</sup> FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

### C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Thus, it is anticipated that use and disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2017, approximately 27.4% of paper and paperboard in municipal solid waste is currently deposited in land disposal sites, 6.7% is combusted, and 65.9% is recycled.<sup>2</sup> The low use level of the FCS in paper and paperboard will not impact the disposal patterns of the products in which the FCS is used.

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

The subject of this notification is a copolymer of acrylamide, 2-methacryloxyethyltrimethyl ammonium chloride, itaconic acid, and N,N'-methylenebisacrylamide. The molecular formula may be expressed as: (C<sub>3</sub>H<sub>5</sub>NO-C<sub>9</sub>H<sub>18</sub>NO<sub>2</sub>Cl-C<sub>5</sub>H<sub>6</sub>O<sub>4</sub>-C<sub>7</sub>H<sub>10</sub>N<sub>2</sub>O<sub>2</sub>). The polymer cannot be represented by a discrete chemical structure due to the presence of multiple monomeric repeating units. Representative repeating unit structures that may be present in the polymer are as follows:



### 6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an EA ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances that indicate any significant adverse environmental impact as a result of

<sup>2</sup> *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](https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf). See Table 1, page 4.

the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS. In these applications, the FCS (*i.e.*, a polymer) is expected to remain with the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will occur by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

As noted above, the FCS is composed of carbon, hydrogen, nitrogen, chlorine, and oxygen, elements that are commonly found in municipal solid waste (carbon, hydrogen, and oxygen) or mitigated via Clean Air Act Regulations (*i.e.*, although hydrogen and chlorine may contribute to hydrogen chloride emissions, MSW incineration units reduce the emissions of harmful pollutants (from <https://www.epa.gov/stationary-sources-air-pollution/small-municipal-waste-combustors-smwc-new-source-performance> and <https://www.epa.gov/stationary-sources-air-pollution/large-municipal-waste-combustors-lmwc-newsources-performance>: "Section 129 of the Clean Air Act (CAA) directs the Administrator to develop regulations under section 111 of the Act limiting emissions of nine air pollutants (*i.e.*, particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from four categories of solid waste incineration units: municipal solid waste; hospital, medical and infectious solid waste; commercial and industrial solid waste; and other solid waste.")). Accordingly, the disposal of the FCS does not threaten a violation of 40 C.F.R. Part 60, which establishes emissions requirements for certain stationary sources, because the FCS is composed of elements commonly found in municipal solid waste (MSW). In addition, the regulations at 40 C.F.R. Part 258 prevent leaching of the FCS from sanitary landfills. More specifically, 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'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). 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 action as appropriate.

The greenhouse gas (GHG) emissions resulting from the disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "established 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 CO<sub>2</sub>-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.

Based on the estimated market volume of the FCS used in the requested applications, 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 food-contact articles containing the FCS in MSW combustion facilities. Further, food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustors, as the FCS contains carbon, oxygen, hydrogen, nitrogen, and chlorine, elements that are commonly found in MSW (carbon, hydrogen, and oxygen) or mitigated via Clean Air Act Regulations (*i.e.*, although hydrogen and chlorine may contribute to hydrogen chloride emissions, MSW incineration units reduce the emissions of harmful pollutants (from <https://www.epa.gov/stationary-sources-air-pollution/small-municipal-waste-combustors-smwc-new-source-performance> and <https://www.epa.gov/stationary-sources-air-pollution/large-municipal-waste-combustors-lmwc-newsources-performance>: “Section 129 of the Clean Air Act (CAA) directs the Administrator to develop regulations under section 111 of the Act limiting emissions of nine air pollutants (*i.e.*, particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from four categories of solid waste incineration units: municipal solid waste; hospital, medical and infectious solid waste; commercial and industrial solid waste; and other solid waste.”)). 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).

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

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 C.F.R. Part 60-compliant operating MSW combustors, and incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

### **B. Water**

No significant quantities of any substance will be added to water systems upon proper incineration of food contact articles that include the FCS. 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 polymer. 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 exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. EPA's regulations at 40 C.F.R. Part 258 require MSW owners to operate their facilities to prevent leaching from sanitary landfills. Furthermore, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when food-contact articles containing the FCS are disposed in sanitary landfills. Thus, there is no expectation of any meaningful exposure of these substances to terrestrial organisms as a result of the proposed use(s) of the FCS.

Considering the foregoing, we respectfully submit that 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 subject polymer in the manufacture of food-contact articles. Therefore, the environmental fate of substances 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(s) of the FCS were identified as discussed under Item 6.

### **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 leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact articles containing 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**

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 and coal. The manufacturer of the FCS polymer will consume comparable amounts of energy and resources as similar products, such as those substances permitted for use in the manufacture of paper and paperboard in 21 C.F.R. § 176.170, already being marketed. This is because the raw materials used in the production of the FCS are commercially manufactured materials that are already 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.

Paper products containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used paper products. Because the FCS is used at a low level in the manufacture of paper products, there will be no impact on current recycling programs.

### **10. Mitigation Measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS when present in finished paper and paperboard. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require mitigation measures.

**11. Alternatives to the Proposed Action**

No significant potential adverse environmental effects are identified in this EA that would necessitate alternative actions to those proposed in this Notification. If the proposed action is not approved, the result would be continued use of the materials that the subject FCS would otherwise replace. Such action would have no significant environmental impact.

**12. List of Preparers**

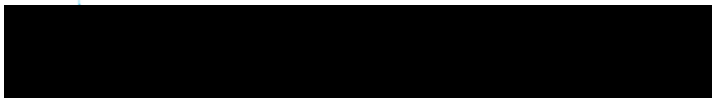
Mitzi Ng Clark, Partner, Keller and Heckman LLP, Three Embarcadero Center, 1420, San Francisco, CA 94111. Over 17 years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Peter Coneski, Ph.D. in Chemistry, Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Over 6 years of experience in preparing Food Additive Petitions and Food Contact Notifications, including the Environmental Assessments for the same.

**13. Certification**

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

Date: March 31, 2020



Mitzi Ng Clark  
Authorized Counsel for Harima Chemicals, Inc./  
Plasmine Technology, Inc.

**14. List of References**

1. FDA's food types and Conditions of Use are defined 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](https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf).

**15. List of Attachments**

Confidential Attachment