Environmental Assessment

1. Date: March 31, 2022

2. Name of Applicant/Notifier: Harima Chemicals, Inc., Plasmine Technology, Inc.

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4. Description of the Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), a copolymer of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), methacrylic acid (CAS Reg. No. 79-41-4), n-butyl acrylate (CAS Reg. No. 141-32-2), methyl methacrylate (CAS Reg. No. 80-62-6), and, optionally, acrylic acid (CAS Reg. No. 79-10-7) and/or α-methylstyrene dimer (CAS Reg. No. 6362-80-7), when used as an emulsifier for wet end chemicals in the manufacture of paper and paperboard. The polymer is intended for use at a maximum level of 0.163% relative to dry paper. The finished materials manufactured with the aid of the FCS are intended for use in contact with all foods 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").

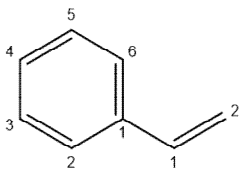
The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.[1] According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted,

[1] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

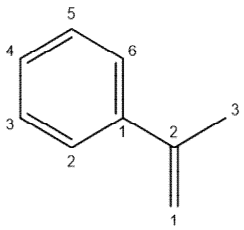
23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[2]

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

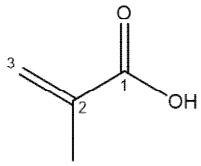
The subject of this Notification is copolymers of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), methacrylic acid (CAS Reg. No. 79-41-4), n-butyl acrylate (CAS Reg. No. 141-32-2), methyl methacrylate (CAS Reg. No. 80-62-6), and, optionally, acrylic acid (CAS Reg. No. 79-10-7) and/or α-methylstyrene dimer (CAS Reg. No. 6362-80-7). 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. Nevertheless, a summary of the structures of the monomers used in the manufacture of this substance are as follows:



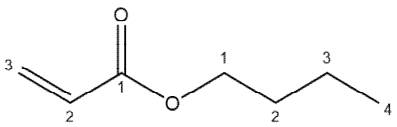
styrene



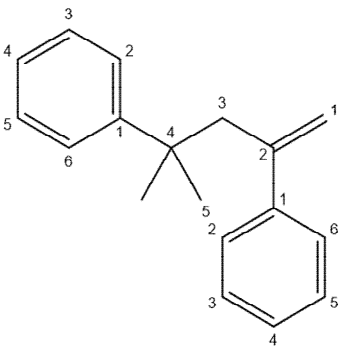
alpha-methylstyrene



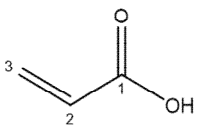
methacrylic acid



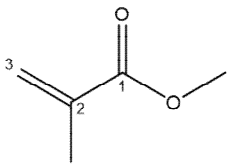
n-butyl acrylate



alpha-methylstyrene dimer



acrylic acid



methyl methacrylate

6. Introduction of Substances into the Environment

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 food-contact materials. The Notifier is not aware of any information to suggest that there are any 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) promulgated by Federal, State, or local environmental

[2] *Id.*

agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that 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.

The FCS is intended for use as an emulsifier for wet end chemicals that are in turn used during the paper manufacturing process. Potential environmental exposure would occur during paper processing and when the paper and paperboard products themselves (as food-contact materials) are disposed by the user.

A. As a Result of Use

When used as intended, it is not reasonable to expect that the FCS would either remain in its entirety with the paper production process water or be entirely substantive to the finished paper. Rather, portions of the FCS will remain with the process water and the remainder will be substantive to the paper. Those portions remaining with the process water will subsequently enter the facility wastewater processing system. Effluent from the pulp and paper processing will be treated via wastewater treatment facilities before release into the environment.[3] For the sake of conservatism, however, in determining the potential environmental impacts occurring as a result of the FCS remaining in the paper production process water, we assume that all of the FCS enters the wastewater. This assumption is a worst-case assumption; in fact, we expect a lesser percentage of the FCS to enter the wastewater.

The intended technical effect of the FCS is to aid with the emulsion of wet end chemicals added to food-contact paper. During the wet-end phase of the papermaking process, the aqueous concentration of solids (fibers and fillers) typically varies between 0.5% and 1.5% by weight.[4] We use the 1.5% concentration for a worst-case assessment.

As the maximum use level of the FCS, relative to dry paper solids, is 0.163%, the aqueous concentration of the FCS in a papermaking facility is anticipated to be no greater than 0.002445%, or 24.45 mg/L (1.5% solids in papermaking process x 0.163% FCS concentration relative to paper solids = 0.002445%). This value represents the maximum environmental introduction concentration (EIC).

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[3] Water-discharging facilities producing pulp, paper, and paperboard are subject to the U.S. Environmental Protection Agency's effluent guidelines and standards under the Clean Water Act, at 40 C.F.R. Part 430.

[4] Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.

Although no specific data exists on the polyanionic FCS,[5] EPA recognizes the appropriateness of evaluating environmental fate using the nearest analog method for this class of polymer (*i.e.*, polyanionic polymers).[6] In this regard, due to the presence of carboxylic acid functionalities in the FCS, the nearest analog class of polymers should be considered to be poly(carboxylic acids). Poly(carboxylic acids) (poly(carboxylates)), in general, do not adversely impact wastewater treatment operations.[7] In fact, the overall removal of high molecular weight polycarboxylates in conventional wastewater treatment has been shown to range from 82% (in a continuous activated sludge test)[8] to 97% (in a lab scale treatment plant test).[9] Conservatively assuming an 80% removal rate, the level of the FCS remaining in treated water after wastewater treatment would be 4.89 mg/L (24.45 mg/L x 20% = 4.89 mg/L). If we then use a 10-fold dilution factor for discharge to surface waters,[10] the estimated environmental concentration in treated waters is 0.489 mg/L.

The estimated environmental concentrations, calculated as described above, are provided in the table below.

Use of the FCS	Use Level	EIC	EEC_{sludge}	EEC_{water}
Emulsifier for wet end chemicals in the manufacture of paper and paperboard	24.45 mg/L	24.45 mg/L	19.56 mg/L	0.489 mg/L

Sludge resulting from wastewater treatment may end up landfilled or land applied.

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[5] The methacrylic acid and/or acrylic acid repeat units found in the FCS polymer are expected to exist primarily in their anionic forms under environmental conditions due to their respective pKa values of 4.65 and 4.25 (*see e.g.,* the National Library of Medicine's PubChem Compound Summaries for methacrylic acid and acrylic acid at https://pubchem.ncbi.nlm.nih.gov/compound/Methacrylic-acid and https://pubchem.ncbi.nlm.nih.gov/compound/Acrylic-acid).

[6] United States Environmental Protection Agency Memorandum: Environmental Concerns of Polymers, February 1, 1991.

[7] Soap and Detergent Association. 1996. Polycarboxylates, pp 3-6.

[8] Opgenorth, H.-J., 1992. Polymeric Materials Polycarboxylates, *The Handbook of Environmental Chemistry, Volume 3, Part F* (N.T. de Oude, ed.) Springer-Verlag, Berlin, 337-350 *as cited in* Soap and Detergent Association. 1996. Polycarboxylates, pp 3-6.

[9] Schumann, H., 1991. Elimination properties of polyelectrolytes in biological wastewater purification processes, *Tenside Surfact. Det. 28*(6): 452-459 *as cited in* Soap and Detergent Association. 1996. Polycarboxylates, pp 3-6.

[10] Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry, 7(2), 107-115.

B. As a Result of Disposal

a. Air

Solid wastes, including disposal by users of paper products generated with the FCS, are expected to be disposed of by either landfill or incineration.

The FCS consists of carbon, hydrogen, and oxygen, elements commonly found in MSW. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide, and that 11.8% of the paper manufactured with the FCS will be combusted.

There is the potential for greenhouse gas (GHG) emissions to result from the use and disposal of the FCS during the incineration of articles containing the FCS in MSW combustion 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) described the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-e emission threshold for required reporting.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment.

Based on the estimated market volume of the FCS used in the requested applications, the expected carbon dioxide equivalent emissions, provided in a 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, hydrogen, and oxygen elements that are commonly found in MSW. Therefore, incineration of the FCS is not expected to 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).

b. Landfill

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).

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of an exposures to any substances in the atmosphere are anticipated due to the proposed use of the polymer. As referenced in the Confidential Attachment, 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 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.

B. Water

As noted in Item 6.A., release of the subject substance to water environments based on its use in paper manufacturing facilities is continuous, and therefore, both acute and chronic exposure to aquatic organisms is possible. Toxicity data for nearest analog high molecular weight polycarboxylates, tabulated below, show no significant acute toxicity concern for aquatic organisms.

Environmental Toxicity Data for Polycarboxylates[11]		
Species	**Endpoint**	**mg/L**
Acute		
Bacteria		
-Robra O_2 consumption test	EC_{10}	>200
-modified O_2 consumption test	EC_{10}	>400
-Bringmann-Kuehn method	EC_{10}	180
-luminous bacteria method	EC_{20}	>200
Algae		
Scenedesmus subspicatus	EC_{10}	>200
Hydra		
Hydra	EC_{50}	136
Daphnia		
Daphnia magna	48-hour EC_{50}	>200
Fish		
Golden orfe	96-hour LC_{50}	>200
Chronic		
Daphnia		
Daphnia magna	21-day NOEC (reproductive)	6.2
Fish		
Zebra fish	6-week NOEC (larval test)	>40
Zebra fish	14-day NOEC (sublethal test)	>40

[11] Chiaudani, G. and Poltronieri, P., 1990. Study on the environmental compatibility of polycarboxylates used in detergent formulations, *Ing. Ambientale*, 11:1-43 and Opgenorth, H.-J.,

The lowest reported acute toxicity threshold is 136 mg/L (Hydra, colony multiplication (EC_{50}).[12] Additionally, the nearest analog shows a lowest chronic No-Observed Effect Concentration (NOEC) of 6.2 mg/L in *Daphnia magna* and much higher levels in fish (>40 mg/L).[13] The reported NOEC for *Daphnia magna* represents a conservative estimate of the lowest aquatic NOEC, since it has been reported that the *Daphnia* test results in unrealistically low toxicity values arising from a physical effect rather than a toxic effect.[14] Nevertheless, even considering this conservatively approximated NOEC, there exists an adequate margin of safety between the NOEC of the most sensitive species and the estimated concentration in natural water (0.489 mg/L).

C. Land

Sludge containing adsorbed FCS may be landfilled or used as agricultural fertilizer. IN the latter case, the concentration of the FCS is sludge is calculated to be no greater than 19.56 mg/kg. Accounting for dilution with base soils, the environmental concentration of the FCS is expected to be significantly lower than 19.56 mg/kg. Environmental data on polycarboxylate analogs shows chronic No-Observed Effect Concentrations (NOEC) in plants of 400 mg/kg, and 96-hr LC_{50} values for earthworms of >1600 mg/kg.[15] AS both values are significantly higher than the maximum concentration of FCS in sludge, *per se*, there is no concern related to land application of sludge containing the FCS.

With regard to environmental introductions as a result of landfilling of sludge and disposal of food-contact materials containing the FCS, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when the FCS is landfilled. 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.

Based on 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 FCS in the manufacture of food-contact paper. 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 of the FCS were identified as discussed under Item 6.

1992. Polymeric Materials Polycarboxylates, *The Handbook of Environmental Chemistry, Volume 3, Part F* (N.T. de Oude, ed.) Springer-Verlag, Berlin, 337-350 *as cited in* Soap and Detergent Association. 1996. Polycarboxylates, pp 3-6.

[12] *Id.*

[13] *Id.*

[14] *See* Opgenorth, s*upra* note 10.

[15] *See* Chiaudani, *supra* note 10.

8. Environmental Effects of Released Substances

As discussed above, only low levels of the FCS are expected to be released into the environment upon the use and disposal of the FCS. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the use and disposal of the FCS and food-contact materials containing the FCS. In addition, the use and disposal of the polymer is not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA'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 contact 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 emulsifiers for wet end chemicals already being marketed, 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.

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 an exceedingly low level in the manufacture of paper products, and is not expected to remain in the finished paper, 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 the FCS when present in wastewater or 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 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

Natalie E. Rainer, J.D., Partner, Keller and Heckman LLP, Three Embarcadero Center Suite 1420, San Francisco, CA 94111. Over 14 years of experience in preparing Food Contact Notifications, including the Environmental Assessments for the same.

Peter N. Coneski, Ph.D. in Chemistry, Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Over 8 years of experience in preparing Food Contact Notifications, including the Environmental Assessments for the same.

13. Certification

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

Date: March 31, 2022

[redacted]

Natalie E. Rainer
Authorized Counsel for Harima Chemicals, Inc. and Plasmine Technology, Inc.

14. References

1. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

2. Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.

3. United States Environmental Protection Agency Memorandum: Environmental Concerns of Polymers, February 1, 1991.

4. Soap and Detergent Association. 1996. Polycarboxylates, pp 3-6.

5. Opgenorth, H.-J., 1992. Polymeric Materials Polycarboxylates, *The Handbook of Environmental Chemistry, Volume 3, Part F* (N.T. de Oude, ed.) Springer-Verlag, Berlin, 337-350.

6. Schumann, H., 1991. Elimination properties of polyelectrolytes in biological wastewater purification processes, *Tenside Surfact. Det. 28*(6): 452-459.

7. Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry, 7(2), 107-115.

8. Chiaudani, G. and Poltronieri, P., 1990. Study on the environmental compatibility of polycarboxylates used in detergent formulations, *Ing. Ambientale,* 11:1-43.

15. Attachment

1. Confidential Attachment