Environmental Assessment

1. Date	November 26, 2019
2. Name of Applicant/Petitioner	Brüggemann Chemical US, Inc.
3. Address	All communications on this matter are to be sent in care of Counsel for Notifier: George G. Misko, Partner Keller and Heckman LLP 1001 G Street, NW, Suite 500 West Washington, D.C. 20001 Telephone: 202-434-4170 E-mail: misko@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), a mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (HSIA; CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (HSOA; CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (SS; CAS Reg. No. 7757-83-7), when used in food-contact materials.

The FCS is intended for use as a reducing agent in emulsion polymerization redox catalyst systems, with the produced polymers emulsions to be used as components of food-contact:

1. pressure-sensitive adhesives compliant with 21 C.F.R. § 175.125;
2. coatings compliant with 21 C.F.R. § 175.300;
3. coatings compliant with 21 C.F.R. § 175.320; and
4. coatings for polyester films.

Food-contact articles containing the polymer emulsions may contact all food types under FDA's Conditions 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 container at time of use"). The FCS is subject to the following limitations:

1. The FCS shall be used at a maximum level of 1.0 percent, based on total monomer weight, when used as a reducing agent in the production of polymers to be used as components of food-contact pressure-sensitive adhesives compliant with 21 C.F.R. § 175.125.

2. The FCS shall be used at a maximum level of 1.0 percent, based on total monomer weight, when used as a reducing agent in the production of acrylic latex polymers to be used as components of food-contact coatings compliant with 21 C.F.R. § 175.300. Food-

contact coatings compliant with 21 C.F.R. § 175.300 that are formed using the FCS shall possess a maximum thickness of 9 microns.

3. The FCS shall be used at a maximum level of 1.0 percent, based on total monomer weight, when used as reducing agent in the production of polymers to be used as components of food-contact coatings compliant with 21 C.F.R. § 175.320 and coatings for polyester films. Food-contact coatings compliant with 21 C.F.R. § 175.320 and coatings for polyester films that are formed using the FCS shall be applied at a maximum rate of 0.5 pounds per ream.

4. The FCS is authorized for use in food-contact applications for infant formula and human milk. When used in infant formula and breastmilk food-contact applications, the FCS is subject to the same use limitations, except that the FCS shall be used at a maximum level of 0.5 percent, based on total monomer weight, when used as a reducing agent in the production of acrylic latex polymers to be used as components of food-contact coatings compliant with 21 C.F.R. § 175.300.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to food-contact polymer and article manufacturers.

B. Need for Action

The FCS is intended to be used as a reducing agent in the production of emulsion polymers that will be used in food-contact materials. The FCS serves to reduce peroxide or persulfate polymerization catalysts to free radical forms, which provide the benefits of lower reaction temperatures and better polymerization reaction control. The FCS may also be used as a "chaser" to push the polymerization to completion.

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. In some of the applications, articles containing the FCS may be collected for recycling (e.g. acrylic coatings for cans). In most of the above applications, the food-contact materials containing the FCS are not expected to be collected for recycling to a significant extent, except potentially as a part of a mixed plastics recycling stream (e.g. coated polyolefin film, and coated polyester film). According to U.S. Environmental Protection Agency (EPA) data for 2015, approximately 52.5% of municipal solids waste is currently deposited in land disposal sites, 12.8% is combusted, and 34.7% is recovered (a combination of waste recovered for recycling and for composting).[1]

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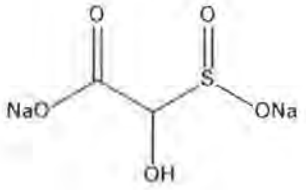
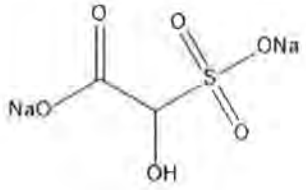
[1] *Advancing Sustainable Materials Management: Facts and Figures 2015*, U.S. Environmental Protection Agency, July 2018, at https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

5. Identification of the Subject of the Proposed Action

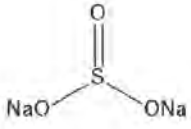
The subject of this notification is a mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (HSIA; CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (HSOA; CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (SS; CAS Reg. No. 7757-83-7). The molecular formulas of the components of the FCS are $C_2H_2O_5S{\cdot}2Na$ (184 g/mol), $C_2H_2O_6S{\cdot}2Na$ (200 g/mol), and Na_2SO_3 (126 g/mol), respectively. The structures of the individual components of this mixture may be represented as follows:



HSIA



HSOA



SS

When the FCS is used as intended, the FCS is oxidized to yield sodium glyoxylate (NaG), sodium oxalate (NaOx), sodium sulfate, sodium formate, and carbon dioxide in the emulsion polymerization. A small fraction of the FCS may remain unoxidized in the finished emulsion, but would continue to oxidize to the products above in the presence of water and oxygen.

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 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 and its oxidation products are expected to be entirely incorporated into finished materials, 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 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, incineration, or to a minor extent, recovery for recycling.

The FCS is composed of carbon, hydrogen, oxygen, sulfur, and sodium; elements that are commonly found in municipal solid waste. The proposed use of the FCS and its corresponding confidential market volume show that the FCS will make up a very small portion of the total MSW currently combusted, estimated to be 12.8% of the 262.43 million tons of waste generated, or 33.6 million tons as of 2015.[2]

Based on the chemical composition of the FCS, the combustion products of the FCS may 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 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_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, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60 and 62, the regulations governing municipal waste combustors, as carbon, hydrogen, oxygen, sulfur and sodium are either typical elements in MSW (i.e., C, H, and O) or mitigated via these Clean Air Act regulations (i.e., although S may contribute to sulfur dioxide or SOX emissions, MSW incineration units reduce the emissions of harmful pollutants), or likely to be part of the ash (i.e., Na). 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.

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[2] *See* footnote 1.

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.

We compared the confidential market volume information for the FCS, contained in a confidential attachment to this Notification, to the annual municipal solid waste (MSW) production (262.43 million tons MSW in 2015), 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.

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. 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. As discussed above under Item 6, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations.

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.

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 FCS in the manufacture of food-contact materials. 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.

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 extractables, if any. 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 materials 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. However, the use of the subject FCS in the preparation of polymer emulsions is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of polymerizations in which similar products that are already on the market are used. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Food-contact materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used materials with or without comparable additives. When the FCS is used in pressure-sensitive adhesives, coatings for polyolefin films, and coatings for polyester films, the finished articles are not anticipated to be recovered for recycling (although coatings for polyolefin films and coating for polyester films may be part of a mixed plastic recycling stream). Such 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 currently used polymerization aids. When the FCS is used in acrylic can coating formulations, where such articles are already collected for recycling, the FCS will be a negligibly small component of such articles, and will replace comparable polymerization aid products. Therefore, 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 within the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No potential 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 action would have no environmental impact.

12. List of Preparers

1. George G. Misko, J.D., Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Mr. Misko has over 30 years of experience drafting Food Additive Petitions, FCN submissions, and Environmental Assessments.

2. Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Dr. Manning has 3 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: November 26, 2019

George G. Misko

[redacted]

Counsel for Brüggemann

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 in Tables 1 and 2 at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: Facts and Figures 2015*, U.S. Environmental Protection Agency, July 2018, at https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

15. Attachments

1. Confidential Attachment to Environmental Assessment