Environmental Assessment

1. Date April 22, 2024

2. Name of Applicant Brüggemann Chemical US, Inc.

3. Address Agent for Notifier:

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4. Description of Proposed Action

a. Requested Action

The action identified in this Food Contact Notification (FCN) is to provide for the use of the food contact substance (FCS) identified as magnesium and zinc complexes with 10-40% hydroxy(sulfinato)acetate, 20-60% hydroxy(sulfonato)acetate, 5-30% glyoxylate, as a reducing agent in emulsion polymerization redox catalyst systems. The FCS will be used at a maximum level of 1.0 percent based on total monomer weight of polymers produced, unless otherwise specified below. The polymers produced using the FCS may contact all food types, under Conditions of Use A through H, as described in Table 2,[1] subject to any limitations on the use of such polymers under the 21 CFR regulations that provide for their intended use.

The FCS may be used in the production of:

1. Food-contact paper and paperboard complying with 21 CFR 176.170 or 176.180.

2. Adhesives complying with 21 CFR 175.105.

3. Pressure-sensitive adhesives complying with 21 CFR 175.125.

4. Repeat use rubber articles complying with 21 CFR 177.2600.

5. Acrylic latex polymers to be used as components of coatings complying with 21 CFR 175.300. Coatings that are formed from the acrylic latex polymers will have a maximum thickness of 9 microns.

[1] FDA's Food Types and Conditions of Use are defined at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

6. Polymers to be used as components of coatings for polyolefin films complying with 21 CFR 175.320. The coatings for polyolefin films will be applied at a maximum rate of 0.8 g/m^2 of film.

7. Polymers to be used as components of coatings for polyester film wherein both the coating and the polyester film comply with regulations under 21 CFR that provide for their intended use. The coatings for polyester films will be applied at a maximum rate of 0.8 g/m^2 of film.

b. Need for Action

The FCS is used as a reducing agent in the production of emulsion polymers that will be used in food contact materials. The FCS is intended to produce free radicals which initiate the polymerization process. The FCS may also be used after the polymerization process to finish or "chase" the reaction to completion by reducing the residual monomer. The food contact articles made from these polymers may include food packaging and repeat-use articles, as well as articles such as utensils, plastic cups and plastic plates.

c. Locations of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS 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. 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). Therefore, it is anticipated that disposal will occur nationwide, with about 80.9% of the materials being deposited in land disposal sites, and about 19.1% combusted.[2]

5. Identification of Substances that are Subject of the Proposed Action

The Chemical Abstracts Service (CAS) name of the FCS is acetic acid, 2-oxo-, reaction products with magnesium hydroxide, sulfur dioxide and zinc.

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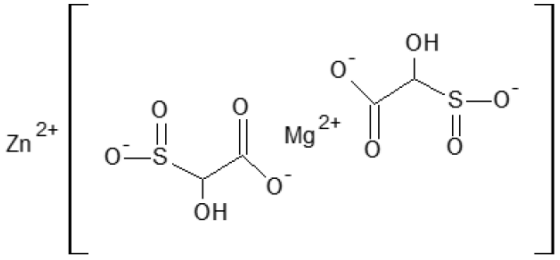
[2] *See* EPA, "Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States," EPA530-F-20-009 (December 2020), *available at* https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

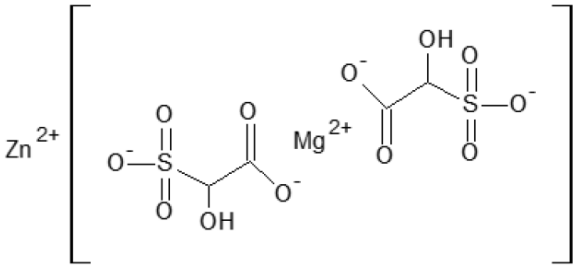
As noted in Table 1 of EPA's fact sheet, of the total 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% was land disposed, 11.8% was combusted, 23.6% was recycled and 8.5% was composted. As the FCS is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we re-calculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

The reaction produces a complex of magnesium zinc hydroxy(sulfonato)acetate ($C_4H_4O_{12}S_2ZnMg$), magnesium zinc hydroxy(sulfinato)acetate ($C_4H_4O_{10}S_2ZnMg$), and magnesium glyoxylate ($C_4H_2O_6Mg$) moieties. Based on analysis, the molar ratio of hydroxy(sulfonato)acetate to hydroxy(sulfinato)acetate to glyoxylate is about 2.4:1.6:1.0.

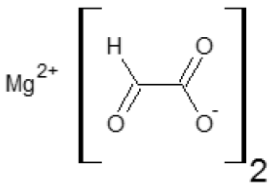
The structures of the individual components of this mixture may be represented as follows:



Magnesium, zinc di(hydroxy(sulfinato)acetate)



Magnesium, zinc di(hydroxy(sulfonato)acetate)



Magnesium glyoxylate

When the FCS is used as intended, the FCS is oxidized to yield magnesium glyoxylate, magnesium oxalate, magnesium sulfate, magnesium formate and carbon dioxide in the emulsion polymer. A small fraction of the FCN may remain unoxidized in the finished emulsion, but would continue to oxidize in the presence of water and oxygen.

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal,

state and local environmental regulations. The notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the 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.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

No significant environmental release is expected upon the use of the FCS in a food contact article. In these applications, the FCS is expected to be entirely incorporated into the finished food contact article; any waste materials generated in this process, *e.g.*, plant scraps, are expected to be recycled by the manufacturer or disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures. Disposal by the ultimate consumer of food-contact materials containing the FCS will be by conventional trash disposal and, hence, primarily by sanitary landfill or incineration. The subject FCS consists of the elements carbon, hydrogen, oxygen, sulfur, magnesium and zinc; elements that are commonly found in municipal waste. Thus, carbon dioxide may form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment and an assessment of these worst-case releases also is included in the confidential appendix.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (EPA) under 40 C.F.R. Part 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 equivalents (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define ‘significantly’ as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. Moreover, 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 appendix to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Furthermore, we have concluded that the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and

incineration of the food contact articles manufactured with the FCS will not cause municipal 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).

Only extremely small amounts, if any, of the FCS's constituents are expected to enter the environment as a result of the landfill disposal of food contact articles, in light of EPA 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 groundwater monitoring systems (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

As described above, articles manufactured with the FCS are expected to be either land-disposed or incinerated as municipal solid waste. These mechanisms of disposal are managed by local, state and federal regulations. Thus, no significant quantities of any substances will be released into the atmospheric, terrestrial or freshwater, estuarine or marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS.

Therefore, there is no expectation of any significant exposure to terrestrial or aquatic organisms as a result of the use and disposal of food contact articles manufactured with the FCS as notified.

8. Environmental Effects of Released Substances

As discussed previously, we do not expect the FCS to be released into the environment. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes, as the FCS is expected to compete with, and to some degree replace similar substances already on the market. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the energy used for the production of the FCS is not significant.

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 discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the FCS. Thus, the use of the FCS as proposed is not expected to result in significant impact to the environment. Therefore, the FCS is not expected to result in environmental issues requiring mitigation measures.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace, including FCSs authorized for the same or substantially similar intended uses under existing effective FCNs and food additive regulations.

12. List of Preparers

Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 with over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 with 30 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: April 22, 2024

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Joan Sylvain Baughan, Partner

14. Attachments

Confidential GHG Calculations