Environmental Assessment

1. Date	October 16, 2020
2. Name of Applicant	Milliken Chemical, Division of Milliken & Co.
3. Address	Agent for Notifier: Joan Sylvain Baughan, Partner Steptoe & Johnson LLP 1330 Connecticut Avenue, N.W. Washington, D.C. 20036

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 bicyclo[2.2.1] heptane- 2,3- dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S) - rel-, (CASRN 839683-04-4), as a nucleating agent, at a maximum level of 0.25 weight percent in all polyolefins in contact with all food types, under Conditions of Use A through H[1]. 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.

b. Need for Action

The FCS is used as a component of finished food contact articles. The FCS reduces the cycle processing time and improves the physical properties of the polyolefin article. The food contact articles manufactured using the FCS 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. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[2]

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[1] *See* https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, Table 2 ("Condition of Use").

[2] *See* EPA, "Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States," EPA530-F-19-007 (November 2019), *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf.

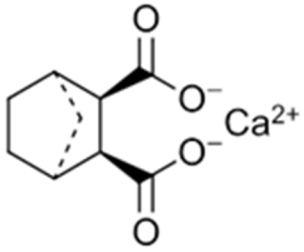
5. Identification of Substances that are Subject of the Proposed Action

The Chemical Abstracts Service (CAS) name of the FCS is bicyclo[2.2.1] heptane- 2,3-dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S) - *rel-*. The CAS Registry No. for the FCS is 839683-04-4.

Chemical Formula: $C_9 H_{10} O_4 Ca$

Molecular weight: 222 g/mol

Structure:



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.

As noted in Table 1 of EPA's fact sheet, of the total 267.79 million tons of municipal solid waste (MSW) generated in 2017, 52.13% was land disposed, 12.71% was combusted, 25.1% was recycled and 10.1% 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 19.6% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 12.71% combusted ÷ (12.71% combusted + 52.13% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

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 and calcium. Thus, carbon dioxide is expected to 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). 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.

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 meaningful substance 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.

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. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of 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

Ms. Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 with over 8 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Ave., N.W., Washington, D.C. 20036 with 29 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: October 16, 2020

[redacted]

Joan Sylvain Baughan, Partner

14. Attachments

Confidential Attachment to the Environmental Assessment