Environmental Assessment

1. Date January 8, 2020

2. Name of Applicant W. R. Grace & Co.-Conn.

3. Address Agent for Notifier:
Mitchell Cheeseman, Ph.D.
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
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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 Silicic acid, aluminum magnesium sodium salt, CAS Reg. No. 12040-43-6, as an acid scavenger in polypropylene (PP), at levels up to 600 parts per million (ppm) by weight, in contact with all food types under Conditions of Use A through H and J, as described in Tables 1 and 2.[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 passivates the residual catalyst used in the manufacture of PP and protects the finished article. The food contact articles 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] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

[2] See the U.S. Environmental Protection Agency's (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), at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

As noted in Table 1 of EPA's fact sheet, of the total 262.4 million tons of municipal solid waste (MSW) generated in 2015, 52.13% was land disposed, 12.71% was combusted, and 35.2% was recovered (a combination of waste

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

The Chemical Abstracts Service (CAS) name of the FCS describes the overall chemical mixture/solid solution, and the name is silicic acid, aluminum magnesium salt, abbreviated as SMAS. The CAS Registry No. for the FCS is 12040-43-6.

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. 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) the 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 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 FCS exists as a complex, inorganic matrix, formed through precipitation. The FCS is not combustible; thus, no airborne emission products are expected to be released into the environment as a result of the incineration of the materials manufactured with the FCS. Since the FCS does not contain constituents that may generate greenhouse gases (GHGs) (e.g, carbon, nitrogen or fluorinated gases) when incinerated at municipal solid waste (MSW) combustion facilities, there is no need to provide a GHG analysis. 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 the

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recovered for recycling and for composting). 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.

Environmental Protection Agency's (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. We note that FDA stated in a telephone conference on December 19, 2019 that it expected no migration of the FCS from polymers in which it is used. Therefore, there is no expectation that the FCS will enter the environment.

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. The FCS does not volatilize and will not combust. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles containing the FCS. As stated above, the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food contact material applications.

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 FCS as demonstrated by the solubility studies that have been carried out. No significant quantities of any substance will be added to these water systems neither upon the proper incineration of the FCS nor upon its disposal in landfills due to the extremely low levels of aqueous migration of its components insolubility.

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 FCS. In particular, the extremely low levels of maximum migration of components of the FCS, demonstrated by its insolubility, indicate that virtually no leaching of the components may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. In addition, we note FDA's statements in a teleconference on December 19, 2019 that no migration of the FCS from polymers containing the FCS is expected. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the FCS as a result of its proposed use.

8. Environmental Effects of Released Substances

As discussed previously, we do not expect the FCS to be released to the environment. Based on these considerations, no 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. In particular, silicon dioxide, sodium aluminosilicate and magnesium silicate are permitted for the same uses as those proposed in this Notification. 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.

11. Alternatives to the Proposed Action

No potential 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.

12. List of Preparers

Ms. Patricia Kinne, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Kinne has over 8 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

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

Date: January 8, 2020

[redacted]

Mitchell Cheeseman, PhD

14. References

U.S. Environmental Protection Agency's (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), at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf