Environmental Assessment

1. Date November 12, 2024

2. Name of Applicant BYK-Chemie GmbH

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 silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate (Type 1, containing fluorine) (CAS Reg. No. 85085-18-3), lithium magnesium sodium silicate (Type 2, without fluorine) (CAS Reg. No. 53320-86-8). The FCS is intended for use as a barrier additive in the production of food-contact: (1) adhesives, and (2) polymeric dispersions used as coatings for plastic, metal, and paper and paperboard, except for use in contact with infant formula and human milk.

The finished adhesives and polymeric coatings used as coatings for plastic, metal, and paper and paperboard containing the FCS may contact all food types, except alcoholic, under Conditions of Use (COU) E through G, as described in Tables 1 and 2.[1] The maximum use level for the FCS in adhesives and coatings will not exceed 50%. The maximum application rate for adhesives or coatings containing the FCS is 10 grams/m^2 (or 6.46 mg/in^2). 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 adhesives and coatings. The FCS can be used as a multifunctional additive mainly to improve thermal and barrier properties, including water and oxidation resistance. The food contact materials include adhesives used in food packaging and coatings applied to food contact paper and paperboard, plastic and metal.

c. Locations of Use/Disposal

The Notifier does not intend to produce finished food contact 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

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

population density and will be widely distributed across the country. 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 FCS is described as silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate (Type 1, containing fluorine) (CAS Reg. No. 85085-18-3), lithium magnesium sodium silicate (Type 2, without fluorine) (CAS Reg. No. 53320-86-8).

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 materials. 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 indicative of any significant adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emission requirements are not provided here.

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 material. In these applications, the FCS is expected to be entirely incorporated into the finished food contact material; 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 an inorganic matrix. The FCS is not combustible; thus, no airborne emission products are expected to be released into the environment as a result of incineration of the materials manufactured with the FCS. Since the FCS does not contain constituents that may

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[2] *See* the U.S. Environmental Protection Agency's (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/production/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, and 32.1% was recovered (a combination of waste 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 19.1% of food-contact materials 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.

generate greenhouse gases (GHGs) when incinerated at a 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 materials, in light of the 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. As the FCS is insoluble, there is assumed to be 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 during use. Thus, no significant quantities of any substances will be released upon the use and disposal of food contact materials 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 due to its relative 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. 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 significant adverse effect on organisms in the environment is expected as a result of the disposal of materials 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 material and 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 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.

12. List of Preparers

Ms. Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, DC 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, DC 20036, with over 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: November 12, 2024

Joan Sylvain Baughan, Partner

14. References

1. U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States* (EPA530-F-20-009), December 2020.

2. U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*.