ENVIRONMENTAL ASSESSMENT

1. Date: February 23, 2024

2. Name of Applicant: Saint-Gobain Ceramics & Plastics, Inc.

3. Address:

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4. Description of the Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), boron nitride (CAS Reg. No. 10043-11-5), which has the molecular formula BN, when used at levels of up to 0.1 weight % as a processing aid in all polymers. Boron nitride is intended for use in polymers that will contact all foods under Conditions of Use A through H. Boron nitride is not intended for use in polymers that contact infant formula and human milk.

This Notification is an expansion of the Notifier's effective Food Contact Notification (FCN) 289, which authorizes the use of the FCS as a processing aid at levels not exceeding 0.1% in the production of olefin polymers under Conditions of Use B through H. Boron nitride is also authorized under FCNs 762, 856, 970, and 1013. Effective FCN 1013 currently permits the FCS for use at levels not exceeding 0.1% in all polymers under Conditions of Use B through H. The material considered in the current Notification would be a competitive replacement for the FCS marketed in the U.S. under FCN 1013.

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 of the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.[1] According to the U.S. Environmental Protection Agency's (EPA) 2018 update regarding municipal solid waste in the United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[2] As the FCS is expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.[3]

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is boron nitride.

Chemical Abstracts Service (CAS) Name: Boron Nitride

CAS Registry Number: 10043-11-5

Molecular Formula: BN

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), 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 aware of no information suggesting the

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[1] *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf (last accessed Feb. 16, 2024).

[2] *Id.*

[3] 11.8% Combusted ÷ (11.8 % combusted + 23.6 % recycled + 50% land disposed) = 13.8% combusted.

existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. In these applications, the FCS (*i.e.*, an additive to polymers) is expected to be entirely incorporated into the finished food-contact materials and is expected to remain with the food-contact materials throughout use in food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

As noted above, the FCS consists of boron nitride. Upon combustion of the polymers containing the FCS, the FCS may not completely combust.[4] The nitrogen content of the FCS has been used to estimate the worst-case potential greenhouse gas (GHG) emissions, as nitrous oxide, derived from combustion of the confidential annual market volume of the FCS (available in the confidential appendix to the EA) and is below 25,000 metric tons carbon dioxide

[4] While data on the air stability of the FCS specifically is not available, data in the literature suggest that the FCS is expected to be stable, under air, at temperatures approaching 1000°C. At higher temperatures, some or all of the FCS may react with the oxygen.

The specific temperature at which boron nitride begins to oxidize when exposed to air/oxygen varies with the specific structure of the boron nitride. For example, cubic boron nitride is stable under air/oxygen up to 1300°C due to a protective surface layer of boric oxide (B_2O_3) (*see* G. E. Spriggs, *Powder Metallurgy Data. Refractory, Hard and Intermetallic Materials* vol. 2A2, "13.5 Properties of diamond and cubic boron nitride" (SpringerMaterials, Landolt-Börnstein) (P. Beiss, R. Ruthardt, H. Warlimont ed. 2002)). Hexagonal-boron nitride platelets are reported to be stable up to approximately 1000°C, where h-BN fibers and nanocrystals are expected to begin oxidizing at temperatures closer to 950°C. *See* Kostoglou, N., Polychronopoulou, K., and Rebholz, C. Thermal and chemical stability of hexagonal boron nitride (h-BN) nanoplatelets, *Vacuum* 112:2015, 42–45, https://doi.org/10.1016/j.vacuum.2014.11.009 and sources cited therein.

A 2021 publication that surveyed municipal waste-to-energy facilities in the United States reports furnace temperatures ranging from 884-1226°C, depending on the waste-to-energy technology used, thus, we consider the possibility that a portion of the FCS will combust. *See* Giraud, R. J., Taylor, P.H., and Huang, C. Combustion operating conditions for municipal Waste-to-Energy facilities in the U.S., *Waste Management* 132:2021, 124–132, https://doi.org/10.1016/j.wasman.2021.07.015.

equivalent (CO2-e) emission per MSW combustor (MSWC) on an annual basis.[5,6] Thus, the concentration of nitrous oxide in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment (*e.g.*, 40 C.F.R. Part 60, 40 C.F.R. Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 C.F.R. 98, "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO2-e threshold for required reporting (40 C.F.R. 98.2), and identifies MSWCs as an included stationary fuel combustion source under 40 C.F.R. 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

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 materials, in light of the EPA regulations governing MSW landfills. EPA regulations require all new 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 as well as "to have ground water monitoring systems and to take corrective action as appropriate" (40 C.F.R. Part 258). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach aquatic or terrestrial environment when disposed via landfill.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Because the FCS is an inorganic compound that decomposes in air at temperatures in excess of 1000°C, the FCS is not expected to readily volatilize. Further, the FCS is unlikely to combust. As indicated above in Item 6, even if the FCS were to combust, no significant adverse environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities. Therefore, combustion of the

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[5] The calculation assumes that 100% of the nitrogen in the FCS will combust to form nitrous oxide.

[6] The U.S. EPA states that there are a total of 75 facilities in the U.S. that recover energy from municipal solid waste. *See* U.S. Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw (last accessed Feb. 16, 2024).

FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. *See* Confidential Attachment for additional details.

B. Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact materials manufactured with 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 concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the insolubility of the FCS and its complete incorporation into food-contact polymers are expected to result in virtually no leaching of the FCS under normal environmental conditions when these food contact materials are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of these substances as a result of the proposed use of the 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.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the EPA'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-contact materials, the production, use, and disposal of the FCS involve the use of natural resources. However, the use of the subject FCS as an additive in food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS will replace, be used as an alternative to, the compositionally identical FCS currently marketed in the U.S. based on the authorization in FCN 1013.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically identical FCS under FCN 1013. Food-contact articles and packaging materials that contain the FCS as a low-level additive are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Further, the presence of the FCS at low levels in the food-contact polymer matrices is not expected to have any significant adverse impact on the recyclability of those food-contact polymers. Thus, no significant impact on current recycling programs is expected based on the use of the FCS.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated containing the FCS. Thus, the proposed use of the FCS is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace (*e.g.*, boron nitride authorized under FCN 1013); such action would have no environmental impact.

12. List of Preparers

Mark Thompson, J.D., Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001. Mr. Thompson has over fifteen years of experience in preparing Food Additive Petitions and Food Contact Notification submissions, including Environmental Assessments.

Kristin P. Wiglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Wiglesworth has over 6 years of experience performing evaluations relating to all aspects of preparing FCNs, 17 years of total experience in FDA regulated industries.

13. Certification

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

Date: February 23, 2024

Mark Thompson

Counsel for Notifier

14. List of References

The following footnotes are found within the Environmental Assessment document.

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf (last accessed Feb. 16, 2024).
2. G. E. Spriggs, *Powder Metallurgy Data. Refractory, Hard and Intermetallic Materials* vol. 2A2, "13.5 Properties of diamond and cubic boron nitride" (SpringerMaterials, Landolt-Börnstein) (P. Beiss, R. Ruthardt, H. Warlimont ed. 2002).
3. Kostoglou, N., Polychronopoulou, K., and Rebholz, C. Thermal and chemical stability of hexagonal boron nitride (h-BN) nanoplatelets, *Vacuum* 112:2015, 42–45, https://doi.org/10.1016/j.vacuum.2014.11.009 and sources cited therein.
4. Giraud, R. J., Taylor, P.H., and Huang, C. Combustion operating conditions for municipal Waste-to-Energy facilities in the U.S., *Waste Management* 132:2021, 124–132, https://doi.org/10.1016/j.wasman.2021.07.015.
5. U.S. Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw (last accessed Feb. 16, 2024).

15. Attachments

1. Confidential Addendum to Environmental Assessment