

1. **Date:** May 18, 2023
2. **Name of Applicant:** Avient Corporation and its stewarded affiliates around the world
3. **Address:** 680 North Rocky River Drive
Berea, Ohio 44017

All communications on this matter are to be sent in care of Counsel for Notifier:

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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) calcium hydride (CAS Reg. No. 7789-78-8) used in conjunction with platinum oxide (CAS Reg. No. 1314-15-4) or zeolite encapsulated platinum (CAS Reg. Nos. 63231-69-6 and 20634-12-2).

The FCS is intended for use in an oxygen scavenging multi-layered inner liner for closures of polyethylene terephthalate (PET) bottles. Specifically, calcium hydride may be used at up to 27% in the non-food contact (active) layer and the platinum source (platinum oxide or zeolite encapsulated platinum) may be used at up to 200 ppm platinum loading in the food-contact (control) layer. Both the non-food contact layer containing calcium hydride and the food-contact barrier layer containing platinum may consist of any polymer regulated for use in contact with the food types and conditions of use listed below for the finished food contact article. This FCS is intended to be used as an alternative to other oxygen scavenger systems such as that described by FCN No. 1224 (sodium borohydride used in conjunction with palladium acetate).

Finished closure liners may be used in contact with all food types under Conditions of Use C (“Hot filled or pasteurized above 150 deg.F”) through G (“Frozen storage (no thermal

treatment in the container”¹).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.

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.² According to the U.S. Environmental Protection Agency’s 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.³ As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate 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.⁴

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

The food-contact substance (FCS) is calcium hydride (CAS Reg. No. 7789-78-8) used in conjunction with platinum oxide (CAS Reg. No. 1314-15-4) or zeolite encapsulated platinum (CAS Reg. Nos. 63231-69-6 and 20634-12-2).

Chemical Abstracts Service (CAS) Name:

Calcium hydride (CAS Reg. No. 7789-78-8) used in conjunction with either platinum oxide (CAS Reg. No. 1314-15-4) or zeolite encapsulated platinum (CAS Reg. Nos. 63231-69-6 and 20634-12-2).

CAS Registry Number: 7789-78-8, 1314-15-4, 63231-69-6, and 20634-12-2

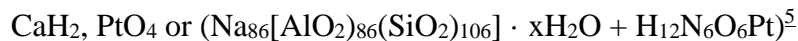
¹ FDA’s food types and Conditions of Use are defined in Tables 1 and 2 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>.

² *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 August 3, 2021).

³ *Id.*

⁴ 11.8% Combusted ÷ (11.8 % combusted + 50% land disposed) = 19.1% combusted.

Structural Formula:



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. Nonetheless, the Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: (1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; (2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or (3) production associated with a 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. 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 closure liners) is expected to be entirely incorporated into the finished food-contact article and is expected to remain with these materials throughout the use of the FCS in the 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.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal (*i.e.*, sanitary landfill or incineration).

The FCS consists of inorganic compounds (calcium hydride, platinum oxide, and zeolite (aluminosilicate) encapsulated platinum).⁶ While reaction with oxygen may occur upon combustion (*e.g.*, formation of calcium oxide), no greenhouse gases are expected to be produced. The FCS does not contain carbon (beyond its presence as a low-level impurity) and, thus, is unlikely to form significant carbon dioxide. The resins used in the closure system (*e.g.*, LDPE and PP/PE elastomer) are already cleared for use in this type of application. Thus, no net increase in greenhouse gas generation is expected if these resins are combusted. Thus, the

⁵ While ammonium platinum nitrate is used in the preparation of the zeolite encapsulated platinum, all nitrogen content (from ammonium and nitrate ions) is expected to be removed during manufacture and will not be present in the species used in the closure. Thus, no nitrogen related greenhouse gases are expected to be formed by the zeolite encapsulated platinum.

⁶ *Id.*

concentrations of greenhouse gases 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. GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. As discussed above, no net increase in greenhouse gas generation is expected if the closure liners are combusted (*see* Confidential Attachment to Environmental Assessment). As no change in GHG emissions is expected, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

EPA regulations require all 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 ground-water monitoring systems (40 C.F.R. Part 258 and Appendix 2). 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 food contact substance 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 consists of inorganic compounds (calcium hydride, platinum oxide, and zeolite (aluminosilicate) encapsulated platinum), the FCS is not expected to readily volatilize. As indicated above in Item 6, no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, combustion of the 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 quantities of any substance will be added to freshwater, estuarine, or marine ecosystems upon the proper incineration of the FCS, nor upon its disposal in landfills. Thus, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the FCS.

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 complete incorporation of the FCS into the closure liners is 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 Environmental Protection Agency'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 it is used at low levels in closure liners and can be used in place of other additives, *see*, for example, FCN 1224.

Manufacture of the FCS and its use in finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of other additives. Closure liners containing the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Thus, there will be no impact on current recycling programs.

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 use of the FCS as proposed 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; such action would have no environmental impact.

12. List of Preparers

Catherine R. Nielsen, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C.20001. Ms. Nielsen has a J.D., with over 30 years of experience drafting food additive petitions and Food Contact Notification (FCN) submissions and 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: May 18, 2023



Catherine R. Nielsen
Counsel for Notifier

14. List of References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, available at: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf (last accessed February 8, 2023).

15. Attachments

1. Confidential Attachment