Environmental Assessment

1. Date	February 26, 2021
2. Name of applicant/notifier	ANHUI GOLD STAR TITANIUM DIOXIDE (GROUP) CO.,LTD.
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4. Description of proposed action

a) Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of Octyltriethoxysilane (OTES)-modified titanium dioxide at a maximum concentration of 25% by weight of the food-contact articles under conditions of use A through H as described in Tables 1 and 2 of CFR 176.170 (c).[1] The food-contact articles containing this FCS are intended to come into contact with all food types, except infant formula and human milk.

b) Need for Action

The FCS is used as a pigment in food-contact articles. The FCS offers several technical properties that make it useful in a variety of food-contact articles applications. In Particular, the FCS is a readily dispersed pigment (readily dispersed into the food-contact polymer).

c) Locations of Use/Disposal

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials and articles. Food contact articles produced with the FCS in the U.S. 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.

According to the U.S. Environmental Protection Agency's (EPA) report December 2020, it is estimated that, of the 14,530,000 tons of plastic containers and packaging

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

present in municipal solid waste (MSW) generated in 2018, approximately 69.4% generally was land disposed, 16.9% was combusted, and 13.6% was recovered for recycling.[2] As the FCS is expected to be disposed primarily by landfill or combustion (i.e., not recovered for recycling or composting), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 80.4% of the materials will be deposited in land disposal sites and about 19.6% will be incinerated.[3]

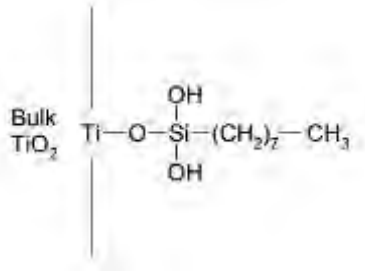
The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact articles in current use. Consequently, there are no special circumstance regarding the environment surrounding either the use or disposal of food-contact articles containing the FCS.

5. Identification of substance that is the subject of the proposed action

The FCS that is the subject of this Notification is Octyltriethoxysilane (OTES)-modified titanium dioxide. Chemical information on this substance is presented below:

CAS Reg. No.: N/A

Structural Formula:



In the manufacturing process, titanium dioxide, OTES and other raw materials were reacted under certain temperature. After the reaction, Octyltriethoxysilane (OTES)-modified titanium dioxide (FCS) was obtained. The FCS has high dispersibility and melt flow with excellent whiteness and blue undertone. The silane modification aims to create a surface that is more compatible with the resin system and enables the FCS to disperse better in resins.

6. Introduction of substances into environment

[2] Table 8 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

[3] This amount is calculated as follows:
16.9% combusted / (16.9% combusted + 69.4% landfilled) = 19.6% combusted. The remaining 80.4% will be land disposed (landfilled).

Usually, in the manufacturing process of food-contact articles, the FCS will be produced to masterbatches at first. After that, the masterbatch will be mixed directly with the target polymer resins to produce colored products for food-contact uses. The use of masterbatch alleviates the issues with the pigment clumping or insufficient dispersions.

a) As a Result of Manufacture

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 articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b) As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process (*e.g.*, plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration. The proposed use of the FCS is the same as FCN 676.

Air (Combustion):

The FCS consists of carbon, hydrogen, oxygen, silicon and titanium. These are elements that are commonly found in municipal solid waste. Considering the proposed use and use level of the FCS described under 4(a)., it can be concluded that the FCS will make up an insignificant portion of the plastic containers and packaging presented in the total municipal solid waste (MSW) currently combusted.[4] The products of complete combustion of the FCS are titanium dioxide, SiO_2, CO_2, and water, materials commonly generated in these facilities. Because the release of CO_2, a greenhouse gas (GHG) is anticipated, a GHG analysis was performed. This analysis is presented in the confidential attachment to

[4] The comparison is contained in the confidential attachment.

the EA and is based upon the elemental composition of the FCS and assumes that 19.6% (described under 4(c).) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis (contained in the confidential attachment to the EA), the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

As such, the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (i.e., 40 CFR 60, 40 CFR 98). Thus, no significant environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

Landfill:

Only extremely low levels, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA's 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 ground-water 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

Based on the extremely low levels of migration and the hydrophobic property of the FCS,[5] the lack of any leaching is especially true considering that the FCS contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

Water

No significant effect on the concentrations of and exposure to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS nor upon its disposal in

[5] Migration data and analysis are contained in the confidential attachment.

landfills due to extremely low levels of aqueous migration of this component.[5]

Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS,[6] to the annual plastic containers and packaging waste (14,530 thousand tons in 2018 from EPA), and concluded that the FCS and the food-contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste in the MSW. Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact resulting from post-consumer disposal of food-contact articles that contain the FCS due to the proposed use.

7. Fate of emitted substances in the environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments. Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental effects of released substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released to the environment during use and disposal of food-contact articles containing the FCS.

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. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations.

9. Use of resources and energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. For example, the effective FCN 676 already permitted the FCS for the same uses as proposed in this Notification. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in

[6] The comparison is contained in the confidential attachment.

place of current materials. Therefore, there will be no impact on current or future recycling programs.

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of other similar pigments. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for similar pigment products.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. 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 proposed action

No 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 which the FCS would otherwise replace; such action would have no environmental impact.

12. List of preparers

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13. Certification

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

14. Attachment

- Confidential Attachment to the Environmental Assessment (Attachment 14 in this Notification)

Date: February 26, 2021

Gabbie Wang, Regulatory analyst

[redacted]

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