Environmental Assessment

1. Date： September 18, 2024*

2. Name of Applicant/Notifier： NIHON KOKEN KOGYO Co., LTD.

3. Address：6-1-2 Ichiban-cho, Tachikawa-shi, Tokyo 190-0033 , Japan

All communication on this matter is to be sent to Agent for the notifier, Kristi O. Smedley, Center for Regulatory Services, Inc., 5200 Wolf Run Shoals Road, Woodbridge, VA 22192-5755 (Telephone No. 703 786-7674).

4. Description of the Proposed Action

a. Proposed Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS), identified as fluorphlogopite-based pearlescent pigments, when used in food-contact materials.

The FCS is intended for use as a colorant for all food-contact polymers, for use at up to 5% by weight in the polymers. Food-contact articles containing the FCS may contact all food types under FDA's Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage), and J (cooking at temperatures exceeding 250 °F.

The finished food-contact materials containing the FCS are not for use in contact with infant formula and human milk, as these uses were not included in the intended use of the FCS.

b. Need for Action

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to food-contact polymer and article manufacturers.

And the FCS is intended to be used as a colorant for polymers that will be used in food-contact materials. The FCS serves to provide color and a pleasing visual appearance to polymeric food-contact articles. The food-contact articles include food packing.

c. Location of Use/Disposal

Since finished food contact materials or articles containing the FCS will be used widely in the United States, the used packaging material and articles will be being distributed widely across the nation depending on the population density of the United States.
Thus, it is anticipated that disposal will occur nationwide.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make minor corrections of an editorial nature.

According to U.S. Environmental Protection Agency (EPA) data for 2018, total 292.4 million tons of municipal solid waste (MSW) was generated in 2018, generally 146.1 million tons (50.0%) of MSW was land disposed, 34.6 million tons (11.8%) was combusted with energy recovery, 69.1 million tons (23.6%) is recycled, 24.9 million tons (8.5%) is composted, and 17.7 million tons of food (6.0 percent) were processed through other food management pathways.[1]

The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the polymeric resins in which they are used.

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

The subject of this notification is synthetic fluorphlogopite-based pearlescent pigments, which exist as powders to be used as colorants for polymers.

The finished fluorphlogopite-based pigments do not have a Chemical Abstracts Service (CAS) Registry Number.

Physically, the pigments consist of fluorphlogopite flakes (i.e. as the substrate/carrier; CAS Reg. No. 12003-38-2) coated with insoluble metal oxide layers of oxides of titanium, tin) on the fluorphlogopite surface. Fluorphlogopite is an analogue of mica (potassium aluminum silicate) in which some of the hydroxyl ions on the aluminum atom have been replaced by fluorine ions.

The chemical formula of fluorphlogopite is Mg3K[AlF2O(SiO3)3] with a molecular weight of 372.63 g/mol. The pearlescent pigments are prepared by calcining titanium, tin into insoluble metal oxides on the fluorphlogopite substrate.

6. Introduction of Substance into the Environment

a. Result of Manufacture

The FCS is manufactured in Japan and the manufacture of the FCS is done under the Japanese Environmental regulations. Thus, the manufacture of the FCS will not affect the adverse environmental impact into the United States environment. _

1. United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Fact Sheet, December 2020, at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

b. Result of Use

No significant environmental release is expected when the FCS is used as colorants in the manufacture of food-contact materials. The FCS is expected to be entirely incorporated into finished materials, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste materials generated during the manufacture of the finished articles, e.g., plant scraps, is expected to be disposed as the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

c. Result of Disposal from Use

Disposal by the ultimate consumer of food contact articles containing the FCS will primarily be by conventional rubbish disposal and, thus, will primarily be by landfill or incineration.

The FCS is a complex matrix of inorganic coated fluorphlogopite, formed at high temperatures, and contains oxides of tin and titanium, and/or other inorganic substances.

The FCS is inorganic and not combustible, and thus, no emission products from the combustion of the FCS are expected to be released into the environment by the incineration of food-contact materials which contain the FCS.

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 CFR Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG". Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of environment".

As the result of this consideration, we inform you that the estimated carbon dioxide equivalent emissions based on the chemical composition of FCS are much less than an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold is inorganic and therefore do not emit carbon dioxide or other greenhouse gases to the environment.
That is, as the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 CFR 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 CFR 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the

landfill disposal of food contact articles comprised of the FCS. 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. Landfills also are required to have groundwater monitoring systems (40 CFR Part 258).

Owners and operators of existing active municipal solid waste landfills constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, but they are required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Substance released into the environment

The main disposal method of the packaging material is expected to be a landfill and some combustion.

7-1. 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 as the FCS does not volatilize and will not combust.

Thus, the concentrations of these substances in the environment will not significantly change by the incineration of FCS used in food contact applications.

As mentioned above, no significant quantities of any substances are released upon the use and disposal of food contact materials containing the FCS.

7-2. Water

No significant effect on the concentrations of, and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of FCS or the disposal of food contact articles made from the FCS since significant quantities of any substance will not be migrated to these water systems neither upon the incineration of the FCS nor upon its disposal in landfills due to the low levels of aqueous solubility of its components.

7-3. 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.

Even though finished food-contact materials containing the FCS are disposed, no leaching of the components may be expected to occur under normal environmental conditions due to the low levels of the migration of components of the FCS because of its insolubility.

Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the

FCS as a result of its proposed use.

Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use.

8. Environmental effects of Released Substances

As discussed above, we do not expect the FCS to be released to the environment.

As the result of these considerations, no significant 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

As same as other food packaging materials, the production, use and disposal of the FCS are used natural resources such as petroleum products, coal, and the like.

However, because FCS are intended to use as colorants for polymers in food contact materials instead of a similar product which are already used on the market (i.e., pigments and other colorants for polymers), the use of FCS as colorants in polymers is not expected to result in a net increase in energy and resource use.

Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Food-contact materials containing the FCS are expected to be disposed by the same patterns when they are disposed the currently used articles or materials with or without comparable colorants.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated with the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternative to the proposed action

No significant adverse effects are identified that would require any action other than those proposed in this notice. If the proposed action were not approved, it would result in the continued use of dyes, pigments, and other colorants for polymers approved under 21 C.F.R Sec. 178.3297 ("polymer colorants") and other similar pigments approved by other FCN. Such action would not have a significant environmental impact.

12. List of preparers

Hiroshi Ishiwata, more than 10 years[1] experience conducting Food Contact Notifications, Technical Director, DJK Corporation, Tokyo, ,Japan

Kristi 0. Smedley, more than 20 years' experience conducting Food Additive Petitions or Food Contact Notifications, Center for Regulatory Services, Inc., VA, U.S.A

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge ofNIHON KOKEN KOGYO Co., LTD.

Akira Hirose
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