Environmental Assessment

1. Date: February 17, 2023 *

2. Name of Applicant/Petitioner: Cinkarna Celje

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

Catherine R. Nielsen, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001
Telephone: 202-434-4140
E-mail: nielsen@khlaw.com

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), n-Octyl phosphonic acid (NOPA)-modified titanium dioxide produced by chemically reacting NOPA (CAS Reg. No. 4724-48-5) with titanium dioxide to achieve a treatment level of 0.85% by weight of NOPA on the pigment. The FCS is for use at a maximum level of 20 percent by weight of finished polymers tin contact with all food types under Conditions of Use (COU) A, B, and H; and a maximum use level of 30 percent by weight of finished polymers in contact with all food types under COU C-G. Use of the colorant is subject to the provisions set forth in 21 CFR 178.3297. 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, NOPA-modified titanium dioxide, is intended to be used as a colorant for food-contact polymers. Treatment of titanium dioxide with NOPA provides hydrophobic properties to the surface of the pigment and enhances the dispersibility of the pigment in the polymer matrix. NOPA-modified TiO_2 is currently cleared for use as a pigment for food-contact polymers under Food Contact Notification (FCN) Nos. 38 and 419. If this notification becomes effective, the NOPA-modified TiO_2 that is the subject of this notification will be available for use as a substitute for the identical pigment that is covered by FCNs 38 and 419, for use in the same food-contact applications.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection

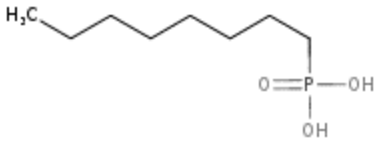
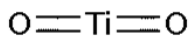
* = Subsequent to this date, this EA was edited using the Adobe text editor tool to make revisions to reflect the final regulatory language of the FCS.

Agency (EPA) data for 2018, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting) and 6.1% is processed through other food management pathways.[1] The low use level of the FCS in food-contact materials will not impact the disposal patterns of the polymeric resins in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is titanium dioxide (CAS Reg. No. 13463-67-7) that has been modified by reaction with n-octyl phosphonic acid (NOPA) (CAS Reg. No. 4724-48-5). The maximum NOPA treatment level is 0.85% by weight of the modified pigment.

The molecular formulas and structures of the starting reactants are as follows:

	n-Octylphosphonic acid	**Titanium dioxide**
Chemical formula	$CH_3(CH_2)_7PO_3H_2$	TiO_2
Molecular structure		

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), 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 not aware of any information to suggest that there are any extraordinary circumstances, such as described under 21 C.F.R. § 25.21(a) and (b), that are in this case indicative of any adverse environmental impact as a result of the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS will be entirely incorporated into finished articles, 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 material generated during the manufacture of the finished articles, *e.g.*, plant scraps, is expected to be disposed as part of the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

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[1] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials 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_ff_fact_sheet.pdf.

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of titanium dioxide modified to contain up to 0.85% of n-octylphosphonic acid. Considering the low organic content, only very low levels of combustion products may be produced when articles containing the FCS are disposed of by means of incineration.[2]

To evaluate the significance of the environmental impact of this notification becoming effective, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are far below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulation (*i.e.*, 40 C.F.R. Parts 60 and 98, and/or relevant state and local laws). Therefore, no significant environmental adverse impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities.

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 articles manufactured with the FCS. 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 CFR 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 food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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[2] The maximum carbon content of the FCS is just 0.42%, calculated based on the molecular formula of NOPA, $C_8H_{19}PO_3$ (MW = 194), and the maximum treatment level of 0.85%: % C = 0.85% NOPA x (8 x 12)/194 = 0.42%.

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, as the FCS is a solid, primarily inorganic particle that does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of 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

As discussed in Item 6., 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 subject FCS.

C. Land

Considering the factors discussed above, no significant effects on the concentration 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 chemical characteristics of the FCS are expected to result in virtually no leaching of FCS components under normal environmental conditions when the food contact articles in which they are contained are disposed of. Furthermore, the very low production of the FCS for use in food-contact applications precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to 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. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and

disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *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 involves the use of natural resources such as petroleum products, coal, and the like. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products already being marketed, including NOPA-modified TiO_2 that is the subject of effective FCNs 38 and 419, for which the FCS will serve as a substitute. 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 of according to the same patterns when they are used in place of the currently used articles with or without comparable additives. Because the FCS is used as a substitute for the chemically identical product that is the subject of FCNs 38 and 419, there will be no significant impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated within the subject FCS. Thus, no mitigation is required.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no environmental impact.

12. List of Preparers

1. Catherine R. Nielsen, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Nielsen has over thirty years of experience drafting Food Additive Petitions, FCN submissions, and Environmental Assessments.

2. Holly H. Foley, Senior Staff Scientist (Food Packaging), Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Holly Foley has over 35 years of experience preparing food additive petitions and Food Contact Notifications, including their 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: February 17, 2023

Catherine R. Nielsen

[redacted]

Counsel for Cinkarna

14. List of References

The following footnotes are found within the Environmental Assessment document:

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: 2018 Fact Sheet. Assessing Trends in Materials 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_ff_fact_sheet.pdf.

15. Attachments

1. Confidential Attachment to Environmental Assessment.