

## ENVIRONMENTAL ASSESSMENT

1. **Date** January 21, 2000
2. **Name of Applicant** Tioxide Group, its subsidiaries and affiliates,
3. **Address** All communications on this matter are to be sent in care of Counsel for applicant, Catherine R. Nielsen, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4140.
4. **Description of the Proposed Action**

The action proposed in this request is the exemption from the need for a food additive regulation, pursuant to 21 C.F.R. § 170.39 (“Threshold of regulation for substances used in food-contact articles”), for *n*-octyl phosphonic acid (NOPA)-modified titanium dioxide when intended for use as a colorant in food-contact polymers at levels not to exceed 30 percent by weight of the polymer under the Food and Drug Administration’s (FDA) Condition of Use C (“Hot filled or pasteurized above 150°F”), or less severe conditions, as described at 21 C.F.R. § 176.170(c), Table 2. Polymers containing NOPA-modified titanium dioxide will be used in contact with all types of food.

We note that, while FDA promulgated regulations, effective August 29, 1997, amending its requirements for environmental assessments (EA's), the Agency has not yet made available guidance documents for preparing EA's under the new regulations. Consequently, the EA presented here has been prepared in accordance with the format requirements that previously appeared at 21 C.F.R. § 25.31a, modified as appropriate to focus on the impact of use and disposal of the subject colorant, in keeping with the new regulations.

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Since the requirements set forth under new Section 25.40 are less extensive than the former requirements, we understand that an EA prepared in accordance with the previous formats will be accepted.

The colorant was the subject of a previous request for the use of NOPA-modified titanium dioxide as a colorant in food-contact polymers at levels not to exceed 5% by weight of the polymer under Condition of Use C or less severe conditions. In response to that request, FDA issued a letter dated March 3, 1998 indicating that the requested use is exempt under 21 C.F.R. § 170.39 from the requirement of being the subject of a food additive listing regulation (*see* Threshold of Regulation File No. 98-001). Thus, the current request seeks only an increase in the maximum use level of NOPA-modified titanium dioxide, namely 30% by weight of polymers.

The use of the colorant in polymers in this request is expected to have no impact on the applications in which the pigmented polymers will be employed. Rather, the colorant will be used in place of other, currently cleared pigments, most of which may be used in food-contact polymers without limitation. Likewise, the colorant's use will have no impact on the disposal of the food-contact materials in which it is used. Thus, final action on the request proposed herein may not reasonably be expected to have any environmental impact from this perspective.

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Tioxide Group, its subsidiaries and affiliates, do not intend to produce finished food packaging materials using the subject NOPA-modified titanium dioxide. Rather, the colorant will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the colorant 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, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.<sup>1/</sup>

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials using from NOPA-modified titanium dioxide.

##### **5. Identification of Substance that Is the Subject of the Proposed Action**

The additive that is the subject of this request is NOPA-modified titanium dioxide, which is manufactured by chemically reacting NOPA (CAS Registry No. 4724-48-5) with titanium dioxide.

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<sup>1/</sup> *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

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**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 articles. Moreover, information available to Tioxide Group, its subsidiaries and affiliates, 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 NOPA-modified titanium dioxide. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject copolymers to fabricate packaging materials. In these applications, the colorant is expected to be entirely incorporated into the finished food package. 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. No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of NOPA-modified titanium dioxide. The colorant is a macroscopic sized pigment that is inorganic in its chemical nature and does not volatilize. Thus, no significant quantities of any substances will be released upon the use of food-contact articles manufactured with this colorant.

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Disposal by the ultimate consumer of food-contact materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. As noted above in Item 4, it is anticipated that disposal will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.

The subject colorant is composed of carbon, oxygen, hydrogen, phosphorus, and titanium. The precise composition of combustion gases during incineration is critically dependent on the temperature of combustion and the amount of available oxygen. When properly incinerated, the subject colorant will generate no hazardous emissions. Because of the nature of the combustion products<sup>2/</sup> and their low levels compared to the amounts currently generated by municipal waste incinerators, the combustion of the polymers is not expected to cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, *e.g.*, 40 C.F.R. part 60 and the relevant State and local laws in the jurisdictions where the polymer will be incinerated.

Only extremely small amounts, if any, of NOPA-modified titanium dioxide constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations

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<sup>2/</sup> Combustion of NOPA-modified titanium dioxide is expected to yield only carbon dioxide, carbon monoxide, and water. When burned the phosphorus component of NOPA will be retained at the pigment surface in the form of phosphate or pyrophosphate. The titanium dioxide and the phosphate/pyrophosphate are inert solids.

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. The lack of any leaching is especially true considering that the subject substance is a macroscopic sized pigment that is inorganic in its chemical nature and it contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>3/</sup>

#### **7. Fate of Emitted Substances in the Environment**

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of the food additive, because, as discussed above, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the colorant. Therefore, the use and disposal of the subject

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<sup>3/</sup> This expectation is confirmed by the results of extraction studies described in the request for exemption from the need for a food additive regulation. As shown there, when extractions were performed, using low density polyethylene (LDPE) samples that contained 30 percent NOPA-modified titanium dioxide by weight of LDPE, with 10%, 50%, and 95% ethanol at 66°C for two hours, followed by extraction at 40°C for up to ten days, NOPA was detected at average levels of 10 parts per billion (ppb) in the 10% ethanol extracts after 10 days, 60.2 ppb in the 50% ethanol extracts, and 38.6 ppb in the 95% ethanol extracts. Thus, the quantity of NOPA-modified titanium dioxide in solid waste deposited in landfills will be extremely small.

colorants are not expected to threaten a violation of the applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. parts 60 and 258.

**8. Environmental Effects of Released Substances**

No information need be provided on the effects of substances released into the environment as the result of use and/or disposal of the food additive, because, as discussed above, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of NOPA-modified titanium dioxide. Therefore, the use and disposal of the substance is not expected to threaten a violation of the applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. parts 60 and 258.

**9. Use of Resources and Energy**

As is the case with other food packaging materials, the production, use and disposal of NOPA-modified titanium dioxide involves the use of natural resources such as titanium-containing ore, petroleum products, coal, and the like. However, the use of the subject colorant in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the colorant is intended to be used in packaging in a manner in which replacement will occur of similar colorants now on the market for use as components of food packaging. Specifically, as discussed in Item 4 above, NOPA-modified titanium dioxide is intended for use as a colorant in food packaging materials. Colorants

currently used in such applications include titanium dioxide that is blended with dispersants such as phosphorylated tall oil fatty acids, dimethylolpropionic acid, or siloxanes and silicones, cetyl methyl, dimethyl, methyl 11-methoxy-11-oxoundecyl.

The replacement of these types of materials by NOPA-modified titanium dioxide is not expected to have any adverse impact on the use of energy and resources. Manufacture of the colorant and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of other colorants. Packaging materials produced from polymers containing NOPA-modified titanium dioxide are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

**10. Mitigation Measures**

No adverse environmental effects are anticipated if this request is approved. Therefore, no mitigation measures are required.

**11. Alternatives to Proposed Action**

Since no potential adverse environmental effects are expected to occur, no alternative actions are necessary.



**12. List of Preparers**

- a. Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

**13. Certification**

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

Date: January 21, 2000

A rectangular box with a red border, used to redact the signature of Catherine R. Nielsen.

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Catherine R. Nielsen  
Counsel for Tioxide Group, its subsidiaries and affiliates