

Environmental Assessment

1. **Date:** October 6, 2006
2. **Name of Applicant/Notifier:** E. I. du Pont de Nemours and Company, Inc.
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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 the clearance of the food-contact substance (FCS), octyltriethoxysilane-modified titanium dioxide, for use as a pigment in food-contact plastics. The pigmented articles will be used for packaging all food types under all conditions of use, as described in Tables 1 and 2 of 21 C.F.R. § 176.170(c).

The FCS offers several technical properties that make it useful in a variety of food packaging applications. In particular, the FCS is a readily dispersed pigment.

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials. 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

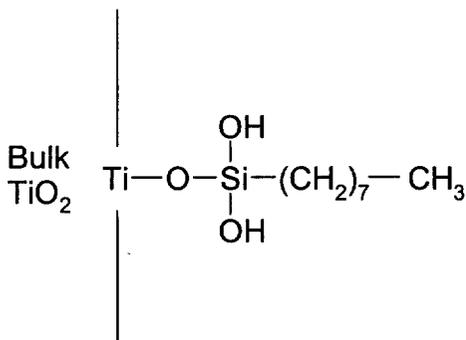
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anticipated that disposal will occur nationwide, with about 76% of the materials deposited in land disposal sites, and about 24% combusted.¹

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 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-modified titanium dioxide with the following structure:



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 the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse

¹ *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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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.

No environmental release is expected upon the use of the FCS as a component of packaging materials. In these applications, the FCS 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 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 FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS consists of octyltriethoxysilane and titanium dioxide. Thus, no toxic combustion products are expected as a result of the proper incineration of the FCS.

Only extremely small amounts, if any, of the FCS's 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 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 groundwater 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 collection 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 FCS contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

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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. The FCS does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles containing the FCS.

The products of complete combustion of the FCS are titanium dioxide, SiO₂, CO₂, and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

(b) Water

No significant effects on the concentrations of and exposures to any substances in freshwater, 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 landfills due to the extremely low levels of aqueous migration of its components.

(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 FCS. In particular, the extremely low levels of maximum migration of components of the FCS, demonstrated by an extraction study, indicate that virtually no leaching of the components may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the very low production of the FCS

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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 the FCS as a result of its proposed use.

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, octyltriethoxysilane-modified titanium dioxide, when used as a pigment in food-contact plastic articles.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials containing the FCS consist of extremely small quantities of combustion products and extractables.

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 FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 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 packaging materials, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like.

However, the use of the FCS in food-contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in place of pigments already

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on the market for use in food packaging. A pigment currently used in such applications includes titanium dioxide that has not been chemically modified.

The partial replacement of this type of material by the 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 packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other pigments. Packaging materials containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. Thus, there will be no 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 food-contact materials containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the materials 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 the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that 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. In view of the

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excellent qualities of the FCS for use in food-contact applications, the fact that the FCS's constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective FCN to permit the use of the FCS as described herein is environmentally safe in every respect.

12. List of Preparers

George G. Misko, Partner, Keller and Heckman LLP

Charles V. Breder, Ph.D., Staff Scientist, Keller and Heckman LLP

13. Certification

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

Date: 10-06-06



George G. Misko
Counsel for E. I. du Pont de Nemours and Company,
Inc.

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