EN

Environmental Assessment

1. **Date:** June 1, 2004

2. **Name of Applicant/Notifier:** E. I. du Pont de Nemours and Company, Inc.

3. **Address:** Chestnut Run Plaza, Building 713/120
4417 Lancaster Pike
Wilmington, Delaware 19880-0713

All communications on this matter are to be sent in care of Counsel for Notifier:
George G. Misko, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, DC 20001
Telephone: (202) 434-4170
Facsimile: (202) 434-4646

4. Description of the Proposed Action

The action requested in this Notification is to establish the clearance of the food-contact substance (FCS), poly(terephthaloyl chloride/*p*-phenylenediamine) (PPDT), for use as a base aramid paper in microwave susceptor applications for contact with all food types.

Food-contact materials produced with the use of the polymer 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 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 prepared from the subject polymer.

---

[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.

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

The FCS that is the subject of this Notification is poly(terephthaloyl chloride/*p*-phenylenediamine) (PPDT) (CASRN 26125-61-1).

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 environmental impact as a result of the manufacture of the subject polymer. 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 polymer to fabricate food-contact materials. In these applications, the polymer is expected to be entirely incorporated into the finished article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed as part of the manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. No toxic combustion products are expected as a result of the proper incineration of the polymer.

Only extremely small amounts, if any, of the polymer'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, as well as 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 subject substance is a high molecular weight polymer that contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

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 subject polymer. The polymer has a high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the polymer.

The products of complete combustion of the polymer are carbon dioxide and water, along with small amounts of nitrogen oxides; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymer in the amounts utilized for food-contact 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 subject

polymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer 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 subject polymer. In particular, the extremely low levels of maximum potential migration of components of the polymer, demonstrated by extraction studies, indicate that virtually no leaching of this substance may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the subject polymer 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 subject polymer, PPDT, in the manufacture of articles intended for use in contact with food.

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-contact materials fabricated with the use of the subject polymer consist of extremely small quantities of combustion products and extractables. The low levels expected in the human diet from the proposed use of the subject polymer may be considered safe even in the absence of toxicology data.

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the polymer. In addition, the use and disposal of the polymer 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-contact materials, the production, use, and disposal of the subject polymer involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer 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 polymer is intended to be used in applications that will replace similar materials now on the market for the intended use. Substances currently used in such applications include metallized polyester film susceptors (*i.e.*, aluminized PET glued to a paperboard substrate).

The partial replacement of these types of materials by the subject polymer is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer, and its conversion to finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers. Moreover, the applications that are the subject of this Notification are not recovered for recycling to a significant extent, but are disposed of by means of landfill and incineration; the subject polymer will not be used to fabricate bottles, which are the types of containers that are recovered for recycling to a significant extent. Materials produced from the subject polymer 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 fabricated from the subject polymer. 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 polymer; and the close similarity of the subject polymer to the materials it is intended to replace. Thus, the use of the polymer 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 subject polymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the subject polymer for use in food-contact applications, the fact that the polymer'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 subject polymer as described herein is environmentally safe in every respect.

12. List of Preparers

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001

13. Certification

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

Date: June 1, 2004

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