Attachment 10 - Environmental Assessment

1.	**Date**	July 17, 2003
2.	**Name of Applicant/Notifier**	DuPont Teijin Films
3.	**Address**	All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Telephone: 202-434-4170.

4. Description of the Proposed Action

The action requested in this Notification is to establish a clearance for polyethylene terephthalate, diethylene glycol-azelaic acid modified, for use as components of food-contact articles. The purpose of the Notification is to permit the use of the subject polymer as a film to fabricate food-contact articles that will be used in contact with all food types under all conditions of use including ovenable applications.

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 being 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

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[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.

are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the subject polymer.

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

The food-contact substance that is the subject of this Notification is polyethylene terephthalate, diethylene glycol-azelaic acid modified. The polymer is produced from terephthalic acid and/or dimethyl terephthalate, azelaic acid, ethylene glycol, and diethylene glycol.

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 food-contact substance. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject polymer to fabricate packaging materials. In these applications, the polymer is expected to be used as a film, and will 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.

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. The subject polymer consists of carbon, hydrogen, and oxygen. The combustion products are expected to be carbon dioxide and water. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of polyethylene terephthalate, diethylene glycol-azelaic acid modified components 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.[2] The lack of any leaching is especially true considering that the food-contact substance is a high-molecular weight polymer that contains only low levels of extractable material even under conditions that exaggerate environmental exposure conditions.[3]

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 diethylene glycol-azelaic acid modified PET. The polymer is of high molecular weight and does not volatilize. Thus, no significant

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[2] 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

[3] This expectation is confirmed by the results of extraction studies described in Attachment 7 of the Notification. As shown there, when film specimens were extracted with 10% ethanol at 40°C for 30 days, there was no detectable migration of oligomers, azelaic acid, or diethylene glycol using methodology sensitive to 0.5 microgram of each analyte per square inch of film. Thus, the quantity of FCS extractives in solid waste deposited in landfills, if any, will be extremely small.

quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this polymer.

The products of complete combustion of the polymer would be carbon dioxide and water; 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 packaging applications.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, 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 FCS, diethylene glycol-azelaic acid modified PET. In particular, the extremely low levels of migration of polymer components demonstrated by the extraction studies indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the low production of the polymer for use in food-contact applications precludes any substantial release to the environment of their components.[4] Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

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[4] Confidential market volume data appear in Attachment 9 of this notification.

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 diethylene glycol-azelaic acid modified PET 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 packaging materials fabricated with the use of the subject polymer consist of extremely small quantities of combustion products and extractables. No adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the polymers. 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 packaging materials, the production, use, and disposal of diethylene glycol-azelaic acid modified PET involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer as a film is not expected to result in a net increase in the use of energy and resources, since the copolymer is intended to be used in place of similar materials now on the market for use in food-contact

articles. Polymers currently used in such applications include, but are not limited to, PET, azelaic acid-modified PET, and DEG-modified PET.[5]

The partial replacement of these types of materials by diethylene glycol-azelaic acid modified PET is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer, and its conversion to finished film food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace. Moreover, similar polymers currently in use for film food packaging materials are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from diethylene glycol-azelaic acid modified PET film 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

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 they are 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.

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[5] The subject food-contact substance differs from the cleared polyesters only in that both DEG and azelaic acid are used together as comonomers. PET produced using either DEG or azelaic acid alone as a comonomer is currently cleared.

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 diethylene glycol-azelaic acid modified PET for use in food-contact applications, the fact that the polymer 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 Food Contact Notification to permit the use of diethylene glycol-azelaic acid modified PET as described herein is environmentally safe in every respect.

12. List of Preparers

Holly Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

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

Date: July 17, 2003

George G. Misko

Counsel for DuPont Teijin Films