Environmental Assessment

1. **Date** July 31, 2002

2. **Name of Notifier** Eastman Chemical Company

3. **Address**

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4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of copolymers of terephthalic acid or dimethyl terephthalate with ethylene glycol and 1,4-cyclohexanedimethanol that are modified with diethylene glycol as a comonomer.

The polymers are intended for use in a variety of food packaging applications. These may include, e.g., exterior shrink wrap involving use in food packaging but no direct food contact, blister packaging and containers such as tubs for use in packaging of foods at room temperature and below or for low temperature hot fill, and shrink wrapping of certain foods where the polymer would be briefly heated to approximately 70° C. The polymers are not expected to be used in fabricating bottles for holding soft drink beverages or similar foods.

The Notifier does not intend to produce finished food packaging materials from the subject polymers. Rather, the polymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polymers 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 are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the polymers.

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

The additives that are the subject of this Notification are copolyesters of dimethyl terephthalate (DMT) or terephthalic acid (TPA) with ethylene glycol (EG), diethylene glycol (DEG), and 1,4-cyclohexanedimethanol (CHDM). This notification is intended to include copolymers for which the sum of 1,4-cyclohexanedimethanol and diethylene glycol may be up to 35 mole percent of the glycol component and diethylene glycol may be up to 12 mole % of the glycol component.

The subject copolymers are closely related to other copolymers already cleared for use in contact with food. For example, copolyesters produced by reaction of DMT or TPA with EG and up to 34 mole-percent of CHDM are cleared under 21 C.F.R. § 177.1315 for contact with food. In addition, copolyesters produced from DMT or TPA, EG, and up to 10 mole-percent of DEG are cleared under Food-Contact Notification No. 85, for which Eastman Chemical Company is one of the notifying parties. The copolyesters that are the subject of this Notification differ from the currently cleared polymers in that they contemplate the combined use of CHDM with non-trivial levels of DEG as comonomers.

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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.

The subject polymers are described more fully in Part II, Section A of this Notification.

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 polymers. 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 polymers to fabricate packaging materials. In these applications, the polymers 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 from the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymers consist of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers in the amounts utilized for food packaging applications.

Only extremely small amounts, if any, of constituents of the subject copolyesters 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 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 substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that exaggerate environmental exposure conditions.[2]

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject copolyesters. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with these polymers.

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 polymers in the amounts utilized for food packaging applications.

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 copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon their disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

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[2] Part II, Section D

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 copolyesters. In particular, the extremely low levels of migration of components of the polymer under exaggerative conditions (compared to environmental conditions), demonstrated by the extraction studies submitted herewith, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

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 copolyesters 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 polymers consist of extremely small quantities of combustion products and extractables. As discussed in Part III, Section B of the Notification, none of the potential migrating components of the polymers present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymers are 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 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 copolymers identified in this Notification involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers 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 copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications. Polymers currently used in the applications in which the polymers are anticipated to be used include other polyester resins, including those that are currently cleared under 21 C.F.R. §177.1315, as well as those that are covered by FCN No. 85.

The replacement of these types of materials by the subject copolyesters is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of the cleared polyester resins. Moreover, the copolyester resins dealt with here will be used in the form of a variety of films and sheets, such as shrink wrap film and blister packaging, and in thermoformed containers such as tubs; the polymers are not expected to be used in the manufacture of bottles used for packaging soft drinks, other beverages, or like products. The types of food packaging materials expected to be produced with the use of the polymers are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from the copolyester resins 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 polymers. 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 polymers; and the close similarity of the subject copolymers to the materials they are intended to replace. Thus, the use of the copolymers 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 Petition. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the copolyester resins described herein 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 their use, the clearance of the use of the polymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

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2. Holley Foley
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13. Certification

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

Date: July 31, 2002

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