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APPENDIX VII

REVISED ENVIRONMENTAL ASSESSMENT

1. Date August 31, 2001

2. Name of Petitioner: Eastman Chemical Company

3. Address: All communications on this matter are to be sent in care of
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Eastman Chemical Company
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4. Description of the Proposed Action

Eastman Chemical Company, is hereby seeking to amend the food additive regulation at 21 CFR 177.1315, "Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers", to include copolyesters containing from 1-100 mole percent of the repeat units derived from 1,4-cyclohexylenedimethylene terephthalate in articles or as components of articles made for food contact purposes. This means that 1,4-cyclohexanedimethanol will comprise 1 to 100 mole percent of the copolymer's diol moiety and that 1,4-cyclohexylenedimethylene groups will comprise 0.5 to 50 mole percent of the entire copolymer taking into consideration both diacid or diester moieties and diol moieties. Also this petition seeks to establish conditions of use for both the currently regulated materials and the proposed materials to include hot fill and pasteurization above 150°F for aqueous/acidic and fatty foods and foods containing up to 13 percent alcohol.

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In addition to the primary objectives of this petition, we also propose additional amendments to 21 CFR 177.1315(b)(1),

(b) (2) and (c). These additional amendments are described in Section B, G and Appendix I. The additional amendment to (b)(1) would increase the permitted level of extractables in the end test using 25% alcohol. The amendment to (b)(2) would eliminate the redundancy which would result from the proposed amendment to (b)(1) to increase the permitted hot-fill temperature for both the non-oriented and oriented articles. The amendments to (c) would amend the list of test solvents for which bishydroxyethyl terephthalate is used as the standard to reflect the current list of solvents used in the tests specified in the regulation, and would add dimethyl terephthalate as an alternative to the cyclic trimer as a standard for migration testing into heptane.

Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers containing up to 34 mole percent 1,4-cyclohexanedimethanol (CHDM) are currently cleared for use under 21 CFR 177.1315(b)1 in non-oriented or oriented (no test for orientation required at (b)1) food-contact applications at temperatures not exceeding 82.2°C (180°F).

Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers containing 1-15 mole percent 1,4-cyclohexanedimethanol are currently cleared for use under 21 CFR 177.1315(b)2 in oriented (test for orientation required at (b)2) food contact applications at temperatures not exceeding 87.8°C (190°F).

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Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers containing up to 5 mole percent 1,4-cyclohexanedimethanol are cleared for use under 21 CFR 177.1315 (b)3 in non-oriented or oriented (no test for orientation required at (b)3) food contact applications for conditions of use set forth in 21 CFR 177.1630 (f), (g), (h), or (j).

For reference while reviewing this petition, those copolyesters containing 1-5 mole % CHDM are designated herein as PET-CHDM copolyesters. Those containing 5 to 50 mole % of CHDM are referred to as PETG copolyesters. The other set of polymers which are part of this Petition contain 50-99 mole percent of the repeat units derived from 1,4-cyclohexylenedimethylene terephthalate and are referred to herein as PCTG copolyesters. Also in this petition, polymers containing 100 mole percent of the repeat units derived from 1,4-cyclohexylenedimethylene terephthalate are referred to herein as PCT polymers.

We incorporate herein by reference food additive petitions submitted by Eastman Chemical Company and identified as FAP 9B3436, FAP 0B3523, FAP 3B3693, FAP 5B3856, and FAP 2B4318.

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The improved properties of the PCTG copolyesters and PCT polymers over other resins are their improved toughness,

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chemical resistance and processability.

There are no new food packaging uses (single or repeat use) currently identified for PETG 5-34 mole percent CHDM polymers at temperatures above 180°F , but we request the regulation be modified to reflect the hot fill temperature use for these materials. Their safety under the conditions of use petitioned for are clearly supported by the migration data submitted in the petition. By increasing the temperature for the already regulated 5-34 mole % CHDM PETG products, we would be creating a consistent and uniform set of conditions of use across the 177.1315 regulation, rather than a fractured set of conditions of use for the various ranges of CHDM compositions. These materials are also technically suitable for applications other than as rigid containers. For example, PETG 6763 (34 mole % CHDM) has the potential to be used as a carrier for concentrate in a container that could be hot filled. Therefore the premarket amendment to the regulation is appropriate.

Food packaging uses for the currently unregulated PETG composition (34-50 mole percent CHDM) are not identified at this time. Again, the request to modify the regulation to cover the span of composition ranges of CHDM is supported by safety data submitted in the petition and will create a more uniform regulation. By having the regulation modified, it will allow the market to determine if it values this product

for the uses covered by the regulation.

PCTG has been identified for single-use food packaging and food-contact items such as clear thermoformed trays and clamshells. PCTG has also been identifed for repeat-use food-contact items such as food serviceware (e.g. small appliances). PCT has been identified for repeat-use food-contact items such as food serviceware (e.g. ladles) that may temporarily see elevated temperatures. PCTG and PCT polymers are intended to compete with and replace PETG polymers in low volume, specialty market applications. PCTG and PCT polymers may also compete in some applications with materials such as PVC, styrenic copolymers, acrylics or polycarbonates, in applications such as interior refrigerator components, point of purchase displays and medical devices. PCTG and PCT polymers are not expected to compete with or replace PET polymers, glass or metal, because they do not have the barrier properties required for use in rigid plastic packaging of most foods. Confidential information on barrier properties of various PETG, PCTG and PCT polymers, confidential economic information, and confidential market information are located in Appendix VIII, Revised Confidential Environmental Information.

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PETG, PCTG and PCT polymers are currently produced by Eastman Chemical Company at manufacturing facilities located at industrial sites, with surrounding environments being

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primarily the large acreage on which the facilities are situated. There is no significant impact on the environment from the production of PETG, PCTG or PCT polymers. PETG, PCTG and PCT should be formed into articles or components of articles at industrial sites particular to the end-use application (e.g. extrusion thermoforming facilities).

The manufacture, use and disposal of articles made from PCTG copolyesters or PCT polymers are essentially the same as for articles made from PETG. Articles made from the subject resins should be used in patterns corresponding to national population density and would be widely distributed throughout the country. Consequently, disposal generally occurs nationwide, with the materials being deposited in landfills, incinerated or recycled (where possible). The types of environments present at or adjacent to disposal locations are the same as for the disposal of any other retail food packaging material currently in use. Therefore, there are no special! environmental considerations regarding the environments surrounding the manufacture, use or disposal of articles made from PCTG or PCT when used as proposed herein.

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In light of the similar physical properties and end uses between PETG, PCTG and PCT, Section 177.1315 is the appropriate regulation to amend to permit all uses of PETG polymers containing up to 50 mole 8 CHDM, PCTG polymers containing up to 99 mole % CHDM and PCT polymers containing

[redacted]

100 mole % CHDM.

5. Identification of the chemical substances that are the subject of the Proposed Action

The materials that are the subject of this Petition are ethylene-1,4-cyclohexylenedimethylene terephthalate copolymer, also called PETG and PCTG copolyesters, depending on the composition; and 1,4-cyclohexylenedimethylene terephthalate polymer, or PCT polymer. The PETG, PCTG and PCT polymers are presently in commerce.

The Chemical Abstract Service (CAS) Registry Number for the copolyester made from dimethyl terephthalate (DMT), ethylene glycol (EG), and 1,4-cyclohexanedimethanol (CHDM) is 25640-14-6. The CAS Registry Number for the copolyester made from terephthalic acid (TPA), EG, and CHDM is 25038-9-1-9.

Under CAS nomenclature these substances are named:

1,4-benzenedicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol (CAS No. 25640-14-6) or 1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol (CAS No. 25038-91-9).

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Other names include:

Poly(ethylene terephthalate-co-1,4-cyclohexylenedimethylene terephthalate) and PETG and PCTG copolyesters.

The CAS Registry number for the polyester made from DMT and CHDM is 25135-20-0. The CAS Registry number for the polyester made from TPA and CHDM is 25037-99-4.

Under CAS nomenclature this substance is named:

1,4-benzenedicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol (CAS No.25135-20-0), or 1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol (CAS N0.25037-99-4).

Other names include:
Poly(1,4-cyclohexylenedimethylene terephthalate); PCT copolyesters.

The empirical formula for repeating units of the copolyesters represented by this petition is $C_XH_YO_4$, where X is 10 to 16 and Y is 8 to 18.

The structural formula of the repeating unit is depicted below:

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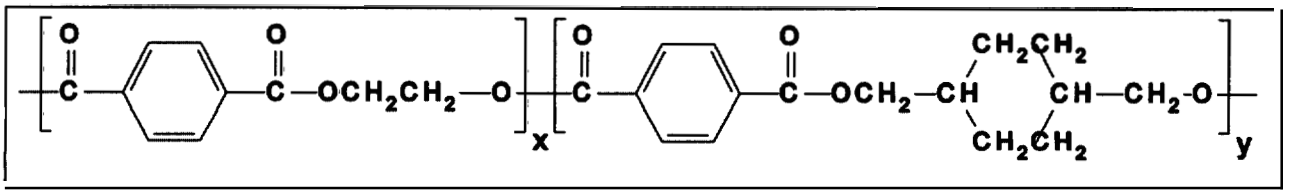

x = 0 to 0.99 and y = 1 to 0.01

The high purity of substances used in the manufacture of the PETG, PCTG copolyesters and PCT polymers precludes inclusion of significant quantities of extraneous materials. The chemistry of polyester synthesis assures the absence of all but minute amounts of monomers and oligomers in polyester polymers suitable for use as packaging material. A complete disclosure of the confidential manufacturing process for PCTG copolyesters and PCT polymers may be found in Appendix **111**.

PETG, PCTG and PCT are produced, stored and typically sold in the form of pellets.

6. Introduction of Substances into the Environment

PETG, PCTG copolyesters and PCT polymers are currently being manufactured. Market projections for PETG, PCTG and PCT are included in Appendix VIII, the entire text of which is claimed confidential.

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The facilities are operated in full compliance with all applicable federal, state and local emissions, environmental and occupational requirements, laws and regulations. Any process volatile emissions are controlled in full compliance

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with all federal, state and local requirements. All solid and liquid wastes produced in the manufacture of PETG and PCTG copolyesters and PCT polymers are disposed of in compliance with applicable laws and regulations of federal, state, and local governments. Any occupational exposure is controlled in ,compliancewith the applicable OSHA requirements and regulations as the processes are enclosed, which limits worker exposure to contact with the finished product during sampling. Compliance with such requirements will not be affected by approval of this Petition. Copies of relevant air and water (NPDES)permits are in Attachment 1 to Appendix VII. 'Thecopy of MSDS's for occupational exposure are in Attachment **IV**, Attachment 4.

The emissions expected during molding of PETG and PCTG copolyesters and PCT polymer into articles will be similar to those of PET resins and will result primarily from spills and from clean-up of storage and processing equipment. In light *of* their non-hazardous nature, any resulting PETG or PCTG copolyesters or PCT polymer waste will be disposed of by processors as non-hazardous waste.

Disposal by the ultimate consumer of food packaging materials fabricated from or containing PETG or PCTG copolyesters or PC'Tpolymer resins would be by return to collection centers or by conventional rubbish disposal, e.g., by open dump, sanitary landfill, or incineration.

[redacted]

PETG, PCTG or PCT resins, like PET resins, are composed only of carbon, oxygen, and hydrogen. The precise composition of combustion gases is critically dependent on the temperature of combustion and the amount of available oxygen. When properly incinerated, PETG and PCTG copolyester and PCT polymer products will generate no hazardous emissions.

Like PET, when articles made from PETG or PCTG copolyesters or PCT polymer resins are added to open dumps and sanitary landfills, no significant amount of leaching of any substance from these materials into the environment is anticipated. This conclusion is based on the low levels of migration of resin components under highly exaggerated exposure conditions (especially from an environmental standpoint) as shown in Section B of the main Petition. The prediction of the total non-volatile extractives that could leach from PETG, PCTG or PCT is listed in Appendix VIII, Revised Confidential Environmental Assessment.

The estimated percentages of the amount of PETG, PCTG and PCT that will enter the waste stream during copolymer/polymer production are listed in Appendix VIII, Revised Confidential Environmental Information.

7. Fate of Emitted Substances in the Environment

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(a) No significant effects on the concentrations and exposures to any substances in the air are anticipated due to the proposed uses of PETG or PCTG copolyesters or PCT polymers. The final products do not volatilize. Any volatile by-products will be controlled in full compliance with all federal, state, and local requirements. The products of complete combustion of the polymer are carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by incineration of the polymer in the amounts utilized for food packaging applications.

(b) No significant effects on the concentrations and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed uses of PETG or PCTG copolyesters or PCT polymers. No substances would be added to these water systems by the production or incineration of the polymer; if deposited in landfills, no leachate is anticipated due **to** the extremely low levels of migration of resin components.

(c) Considering the factors discussed above, no significant effect on the concentrations and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed uses of PETG or PCTG copolyester or PCT polymers.

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8. Environmental Effects of Released Substances

Based on the analysis of extracts performed in the report in Appendix V, Attachment 4, PETG and PCTG copolyesters and PCT polymer extracts are comprised of low molecular weight ester moieties (that are a mixture of oligomers derived from the reaction of CHDM, EG (ethylene glycol), and DMT (dimethyl terephthalate) or TPA (terephthalic acid)), which are similar to those from PET. These moieties are polyester species which are safe as shown by the history of PET and PETG in commerce, and by previously referenced FAP's. The glycol CHDM is safe as demonstrated by the toxicity data in Appendix VI, Attachment 1.

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Therefore, based on the safety of the polyester moieties and the glycol (CHDM), PCTG copolyester and PCT polymer resins have an extremely low level of toxicity, as further supported by a toxicological study finding that the oral LD_{50} of PETG copolyester extracts in rats and mice exceeds 3200 mg/kg (FAP 9B3436, Heading F, Enclosure 1, Acute Oral LD50 PETG T2(31)16 and cyclic trimer). No adverse effects on animal or plant life can be expected from release of products of complete combustion of PETG, PCTG or PCT copolyesters. Nor can adverse effects be expected from disposal of these chemically inert products in landfills. Thus, no adverse environmental impact can reasonably be anticipated from substances produced

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as a result of the proposed uses of PETG or PCTG copolyester or PCT polymer resins.

9. Use of Resources and Energy

The production, use and disposal of PETG, PCTG and PCT polymer resins involve the use of natural resources such as petroleum products, coal, and the like. However, the consumption of natural resources can be partially offset by the production of energy for industrial use from incineration of the used articles in properly designed facilities. In light of its chemical composition, the utilization of petroleum feedstocks and energy in the production, use and disposal of PCTG copolyester and PCT polymer products will be similar to that of PETG.

10. Mitigation Measures

Since no adverse environmental effects have been identified, this format item need not be addressed.

11. Alternatives to the Proposed Action

Since no adverse environmental effects have been identified, this format item need not be addressed.

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12. List,of Preparers

Lacy V. Banko
B.S. Industrial Engineering
Senior Technical Representative

Waylon L. Jenkins
Ph.D. Chemistry
Technical Associate

13. Certification

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

Date: August 31, 2001

Signature: Mary G. Schurger

M. G. Schurger

Title: Director, Product Safety and Regulatory Programs

14. Attachments to Appendix VII

Pertinent operating permits for the Eastman Chemical Company plant are attached.

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