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APPENDIX VII

REVISED ENVIRONMENTAL ASSESSMENT FOR FCN 179

(converted from FAP 4B4427)

1. Date — December 12, 2001

2. Name of Notifier: — Eastman Chemical Company

3. Address: — All communications on this matter are to be sent in care of:

W. L. Jenkins
Eastman Chemical Company
P. O. Box 431
Kingsport, TN 37662
Telephone: (423) 229-3345

4. Description of the Proposed Action

a. **Requested approval:**

Identity:

Copolymers and polymers (non-oriented or oriented in finished form) made from reaction of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 0 mole percent of ethylene glycol and 1 to 100 mole percent of 1,4-cyclohexanedimethanol (70 percent trans isomer, 30 percent cis isomer)

Use:

For use as films or articles or components of films or articles intended for contact with aqueous, acidic, low-alcohol (up to 15%), and fatty foods under conditions of use C through H as described in 21 CFR 176.170(c), Table 2, and for use in contact with foods containing up to 25% alcohol under conditions of use E through G as described in 21 CFR 176.170(c), Table 2.

Limitations:

The polymer shall meet the inherent viscosity specification in 21 CFR 177.1315(b)(1) and the polymer in the finished form shall meet the following extractives specifications based on the intended use:

(1) for use in contact with aqueous, acidic and low alcohol (up to 15%) foods under conditions of use C through H, the finished article shall meet the maximum extractable fractions as specified in 21 CFR 177.1315(b)(1) when tested with water and 3% acetic acid

(2) for use in contact with fatty foods under conditions of use C through H, the finished article shall meet the maximum extractable fractions as specified in 21 CFR 177.1315(b)(1) when tested with n-heptane

(3) for use in contact with alcoholic foods containing more than 15% but not more than 25% alcohol, the maximum extractable fraction shall not exceed 2 micrograms per square inch when tested using 25% ethanol as described in 21 CFR 177.1315(b)(1)

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b. **Need for action**: The food contact substance that is the subject of this notification is not intended to have a technical effect in or on food. The polymers that are the subject of this notification provide a combination of toughness, chemical resistance and processability, which

offers advantages in certain food contact applications. The intended uses are further described below.

For convenience in the following discussion, those copolyesters containing 1-5 mole % 1,4-cyclohexanedimethanol (CHDM) based on the glycol component of the polymer are designated herein as PET-CHDM copolyesters. Those containing 5 to 50 mole % of CHDM are referred to as PETG copolyesters. Polymers that contain 50-99 mole percent of the repeat units derived from 1,4-cyclohexylenedimethylene terephthalate are referred to herein as PCTG copolyesters. Polymers containing 100 mole percent of the repeat units derived from 1,4-cyclohexylenedimethylene terephthalate are referred to herein as PCT polymers.

PCTG and PCT polymers are not currently regulated in 21 CFR part 177. Potential applications for PCTG polymers have been identified for single-use food packaging and food-contact items such as clear thermoformed trays and clamshells. PCTG may also be used for repeat-use food-contact items such as food serviceware (e.g. small appliances, pitchers, etc.). PCT may be used for repeat-use food-contact items such as food serviceware (e.g. ladles, spoons, spatulas, etc.) that may temporarily experience 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 with materials such as PVC, styrenic copolymers, acrylics or polycarbonates in some

applications such as interior refrigerator components and point of purchase displays.

PETG copolyesters containing up to 34 mole % CHDM are currently regulated in 21 CFR 177.1315(b)(1) for use in most food contact applications with hot fill temperatures of up to 180° F. This notification will slightly expand the conditions of use for these copolymers to permit higher temperatures and to remove the exclusion of contact with carbonated beverages that is currently present in 21 CFR 177.1315(b)(1). These polymers are technically suitable for some applications that will be covered by this notification but not by 21 CFR 177.1315(b)(1). For example, a copolyester modified with 31 mole % CHDM may be used as a carrier for a color concentrate to be used in a container that could be hot filled at temperatures above 180° F. Also, the language of 21 CFR 177.1315(b)(1)) excludes contact with carbonated beverages. However, unoriented articles made from copolyesters in this composition range may be used in short term contact with carbonated beverages or beer in applications such as dispensing equipment where barrier properties are not important.

Specific food packaging uses for the currently unregulated PETG composition (34-50 mole percent CHDM) are not identified at this time. The request to notify polymers to cover the span of composition ranges of CHDM is supported by safety

data submitted in the notification. By notifying the range of compositions, the market will determine if there are cost effective applications for copolyesters in this composition range.

c. **Locations of use:**

The use sites for these polymers when used for food contact applications will be food-packaging production sites, food packaging sites, food distribution sites, and places where consumers prepare and ingest food and discard packaging, e.g. homes or restaurants. Because the subject polymers are meant to be incorporated into and function in finished food contact articles and can be expected to remain with the articles through disposal, environmental introductions at use sites should be minimal.

d. **Locations of disposal:**

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).

5. <u>Identification of the chemical substances that are the subject of the Proposed Action</u>

The materials that are the subject of this notification are ethylene-1,4-cyclohexylenedimethylene terephthalate copolymer, also referred to in this notification as PETG and PCTG copolyesters, depending on the composition; and 1,4-cyclohexylenedimethylene terephthalate polymer, also referred to in this notification as PCT polymer. 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).

Other names include:

Poly(ethylene terephthalate-co-1,4-cyclohexylenedimethylene terephthalate)

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.

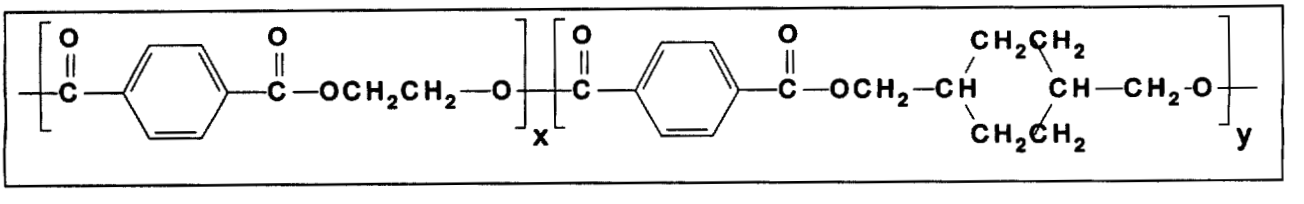
Under CAS nomenclature this substance is named:

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 NO.25037-99-4).

Other names include:
Poly(1,4-cyclohexylenedimethylene terephthalate)

The empirical formula for repeating units of the copolyesters represented by this notification 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:



x = 0 to 0.99 and y = 1 to 0.01

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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 III.

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

6. Environmental Consequences of the Proposed Action:

a. **Environmental consequences of manufacturing:** There are no extraordinary circumstances that apply to the manufacture of the polymers that are the subject of this notification.

b. **Environmental consequences of use:** Little or no introduction of the polymers that are the subject of this notification into the environment will result from use in manufacturing food packaging or other food contact articles because these polymers are almost completely incorporated into the food contact articles and are expected to remain with the food contact articles throughout their use.

c. **Environmental consequences of disposal:**

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Disposal by the ultimate consumer of food packaging materials

fabricated from or containing PETG or PCTG copolyesters or PCT polymer resins would be by return to collection centers or by conventional rubbish disposal, e.g., by sanitary landfill or incineration.

PETG, PCTG or PCT resins, like PET resins, are composed 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 not generate hazardous emissions.

Like PET, when articles made from PETG or PCTG copolyesters or PCT polymer resins are added to 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 notification (originally filed as FAP 4B4427). The estimation 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 are listed in Appendix VIII, Revised Confidential Environmental Information.

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.

We conclude that there will be essentially no changes in the disposal patterns of food-packaging materials or other food contact articles as a result of this notification, because the articles made with the subject polymers will be competing with and replacing only relatively small volumes of similar articles, that both sets of these articles will be managed in the same manner in municipal solid waste systems, and the energy usage associated with the two sets of articles will be essentially the same.

7. Mitigation Measures

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

8. Alternatives to the Proposed Action

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Since no adverse environmental effects have been identified,

this format item need not be addressed.

9. List of Preparers

Waylon L. Jenkins

Ph.D. Chemistry

Technical Associate

10. Certification

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

Date: 12/14/01

Signature:

M. G. Schürger

Title: Director, Product Safety and Regulatory Programs

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