

Environmental Assessment

1. **Date** October 8, 2003
2. **Name of Applicant/Notifier** The Dow Chemical Company
3. **Address** All communications on this matter are to be sent to Ms. Lori Lickly, The Dow Chemical Company, 1803 Building, Midland, Michigan 48674.
Telephone: (986) 638-6231
4. **Description of the Proposed Action**

The action requested in this Notification is to permit the use in indirect food additive applications of polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified) prepared by the condensation of dimethyl terephthalate or terephthalic acid and ethylene glycol with one or more of the following: dimethyl isophthalate, isophthalic acid, and diethylene glycol. The finished polymer shall contain a total of not more than 10 mole-percent of diethylene glycol and isophthalate units, with the diethylene glycol content expressed as a mole-percent of the total glycol units and the isophthalate content expressed as a mole-percent of the total isophthalate/terephthalate units. These materials would be used in films or articles intended for contact with aqueous, acidic, low-alcohol, and fatty foods under conditions of use A through H as described in 21 CFR §176.170(c), Table 2, and for use in contact with high-alcohol foods under conditions of use E through G as described in 21 CFR §176.170(c), Table 2.

The subject PET copolyesters are not intended to be used in food or to have any effect in or on food. Rather, they are intended to be used in the manufacture of materials, including "films" and "bottles", utilized in packaging, transporting, processing, and storing foods. The minute level at which polyester oligomers or residual starting substances may migrate to contacted food from the finished articles is incidental to the proposed use of the polymers.

Food-contact materials produced from the copolyesters are expected to be used in the same type of applications, and with the same type of food, as are polyethylene phthalate polymers currently listed in 21 C.F.R. § 177.1630 and FCN 85. Thus, the copolyesters are expected to be used in a variety of forms, including bottles, sheets, and films, in which the food-contact article's thickness will vary. Both single and repeated use articles may be produced using these materials.

Polyethylene terephthalate has well-established desirable properties for use in food packaging. These include, e.g., excellent clarity, good gas barrier properties, unbreakability, and the

capability to withstand exposure to food at elevated temperatures. The characteristics of the polymer may be modified by the addition of modifying monomers to optimize properties for specific applications. Thus, diethylene glycol and isophthalic acid may be added to bring about a reduction in the rate or degree of crystallization and/or to reduce the polymer melting point. These modifications are generally intended to facilitate processing of the polymer to form food-packaging articles, as they allow the use of milder conditions in the converting step. The reduction in crystallization rate is also necessary to allow the manufacture of thick articles, as required for the production of refillable bottles. The subject PET copolyesters are expected to substitute for traditional polyester polymers in existing applications.

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 the materials ultimately being landfilled, incinerated, or recycled. The patterns of disposal are expected to be comparable to current disposal patterns for PET bottles, as discussed in Item 9 below.

Environments potentially affected by disposal are watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from incineration sites. Disposal releases of the subject polymers should be equivalent to any releases from disposal of regulated polyethylene terephthalate polymers.

Polyethylene terephthalate copolymers are now resin identification coded at "PETE-1," and are routinely collected for recycling. The presence of the proposed additional low levels of bound IPA and DEG polymer units in PET polymers in the recycle stream will have no adverse effects on current "depolymerization" procedures, such as methanolysis or glycolysis, used to treat the recycled polyesters, since these are currently present in the polyethylene terephthalate polymers being recycled. In addition, testing described in Item 9 below demonstrates that containers produced from the subject copolyesters may successfully be included in general PET recycling streams with no adverse effect on the properties of the recycled product. For these reasons, the use of PET copolyesters in the production of food containers is not expected to have any adverse impact on current or future recycling systems.

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

The additives that are the subject of this notification are certain PET copolyesters, specifically copolymers manufactured by the condensation of terephthalic acid with ethylene glycol, modified by the use of isophthalic acid and/or diethylene glycol as comonomers. In the preparations of these polymers, terephthalic acid may be substituted by dimethyl terephthalate and isophthalic acid by dimethyl isophthalate. The finished polymers will contain no more than 10 mole-percent isophthalate and diethylene glycol units, with the isophthalate content expressed as mole-percent of total phthalate units, and the diethylene glycol content expressed as mole-percent of total glycol units. For purposes of the notification language they are

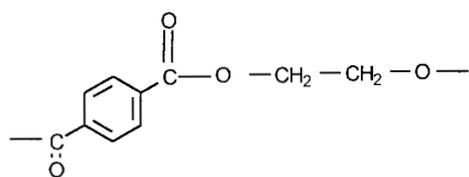
identified as polyethylene terephthalate copolyesters (diethylene-glycol-isophthalate modified). They are generally referred to herein as PET copolyesters.

As the subject copolyesters may be produced by the reaction of a variety of starting monomers, no single polymer identity, or corresponding Chemical Abstracts Service Registry Number (CASRN) can be given to cover all the varying starting monomer combinations. A series of copolyesters are identified in Table I for the various potential combinations of monomers. Only polymers prepared from terephthalic and/or isophthalic acid appear on the table, which is however not intended to restrict the combinations in which the various starting reactants may be used to manufacture the finished polymer, as polymers prepared from dimethyl terephthalate and/or isophthalate will be identical to those prepared from the corresponding acids.

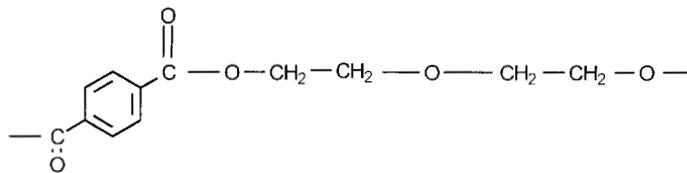
Table I
Copolyester Identities for Various Monomer Combinations

Starting monomers	CASRN	CAS Nomenclature; Chemical Formula
Terephthalic acid Ethylene glycol	25038-59-9	1,4-benzenedicarboxylic acid, polymer with 1,2-ethanediol; $(C_8H_6O_4 \cdot C_2H_6O_2)_x$
Terephthalic acid Ethylene glycol Diethylene glycol	25052-77-1	1,4-benzenedicarboxylic acid, polymer with 1,2-ethanediol and 2,2'-oxobis[ethanol]; $(C_8H_6O_4 \cdot C_2H_6O_2 \cdot C_4H_{10}O_3)_x$
Terephthalic acid Isophthalic acid Ethylene glycol	24938-04-3	1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid and 1,2-ethanediol; $(C_8H_6O_4 \cdot C_8H_6O_4 \cdot C_2H_6O_2)_x$
Terephthalic acid Isophthalic acid Ethylene glycol Diethylene glycol	27027-87-8	1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,2-ethanediol and 2,2'-oxobis[ethanol]; $(C_8H_6O_4 \cdot C_8H_6O_4 \cdot C_2H_6O_2 \cdot C_4H_{10}O_3)_x$

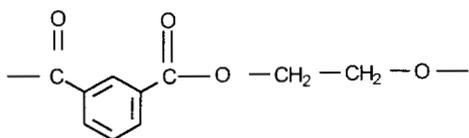
The general structure of these copolyesters will consist of terephthaloyl or isophthaloyl moieties alternating with ethylene glycol or diethylene glycol moieties. The terephthaloyl and isophthaloyl groups are randomly distributed through the polymer chain, as the ethylene and diethylene glycol groups. The various potential polymer repeating units may be depicted as represented in Figure 1, where terephthaloyl and isophthaloyl moieties are labeled as "TPA" and "IPA", while ethylene glycol and diethylene glycol groups are depicted as "EG" and "DEG", respectively.

Figure 1**Repeating Units in the Macromolecular Backbone**

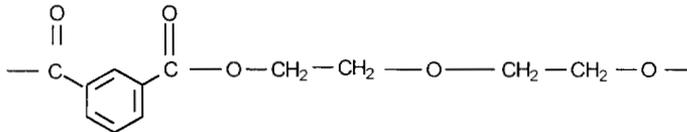
TPA - EG



TPA - DEG



IPA - EG



IPA - DEG

To further identify the range of polymer compositions that are intended to be encompassed in this notification, Table II sets forth the specific identities of the starting monomers, including CASRNs, and the permitted content range in the polymer for each component, expressed in terms of mole-percent of total iso/terephthaloyl moieties and mole-percent of total glycol moieties, as appropriate¹. The weight-percent of the various monomers, defined as the mass of free monomers (in grams) obtained from the complete hydrolysis of 100 grams of polymer, is also indicated. Although not explicitly noted in Table II, only those combinations of DEG and IPA concentrations that will result in finished polymers containing no more than 10 mole-percent isophthalate and diethylene glycol units will be used in the manufacture of the subject copolyesters.

¹ Clearly acid moieties (terephthalic and isophthalic) sum to 100%, and the same is true for glycol moieties. Therefore, it is not surprising that the mole-percents in Table II sum to 200%.

Table II
Identity of the Starting Monomers

Chemical name	Acronym	CASRN	Polymer composition range	
			Weight-percent	Mole-percent
Terephthalic acid (1,4-benzenedicarboxylic acid)	TPA	100-21-0	79.1 – 86.1	91.9 – 100.0
Isophthalic acid (1,3-benzenedicarboxylic acid)	IPA	121-91-5	0.0 – 7.0	0.0 – 8.1
Ethylene glycol (1,2-ethanediol)	EG	107-21-1	28.5 – 31.6	90.2 – 98.2
Diethylene glycol (2,2'-oxobis[ethanol])	DEG	111-46-6	1.0 – 5.3	1.8 – 9.8

The composition range for DEG does not start at zero, because some DEG is unavoidably formed from EG during the polycondensation reaction, even if no virgin DEG is fed. The usual amount of DEG present when no virgin glycol is voluntarily used is approximately 1% by weight.

The high purity of substances used in the manufacture of PET copolyesters precludes inclusion of significant quantities of extraneous materials as impurities. The chemistry of the polyester synthesis assures the absence of all but minute amounts of monomers and oligomers in polyester polymers suitable for use as packaging materials.

6. Introduction of Substances into the Environment

Format Item 6 from the Environmental Assessment for FCN 85 (Dated July 24, 2000, and submitted by Keller & Heckman LLP on behalf of the Notifier: Coalition on PET Safety) is incorporated into this EA with the exception of paragraph 9, which is replaced with:

When food packaging materials made from the subject copolyester 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 exaggerated exposure conditions (from an environmental standpoint) as shown in Part II, Section F of the Notification (which references Section D and Appendices II, III and IV of FCN 85, incorporated herein by reference). To summarize these data, the maximum quantity of phthaloyl moieties found to migrate when the subject copolyesters were exposed to 8% ethanol at 120 °F for 30 days was 0.37 µg/in² of contacted surface. It should be noted that comparable levels of total

extractives were determined for a range of polyester compositions that included maximum DEG and IPA levels as well as PET containing currently permitted and/or no DEG or IPA. Therefore, any leaching that does occur from newly cleared copolyesters will be instead of (rather than in addition to) identical leachate from currently regulated polyesters. In addition, the copolyesters that are the subject of this Notification are identical to those that are covered by effective FCN 85.

The Attachment to the EA for FCN 85 entitled "Plastic Pellets in the Aquatic Environment: Sources and Recommendations," prepared by Battelle Ocean Sciences for the Oceans and Coastal Protection Division, Office of Water (HH556F), Environmental Protection Agency, Washington, D.C., December 1992, is incorporated herein by reference.

The "Supplement to the Environmental Assessment for Premarket Notification FCN No. 85," prepared by Elizabeth Ann Cox of the Food and Drug Administration on September 22, 2000, is incorporated herein by reference.

7. Fate of Emitted Substances in the Environment

Format Item 7 from the Environmental Assessment for FCN 85 (Dated July 24, 2000, and submitted by Keller & Heckman LLP on behalf of the Notifier: Coalition on PET Safety) is incorporated into this EA by reference.

8. Environmental Effects of Released Substances

Format Item 8 from the Environmental Assessment for FCN 85 (Dated July 24, 2000, and submitted by Keller & Heckman LLP on behalf of the Notifier: Coalition on PET Safety) is incorporated into this EA by reference.

9. Use of Resources and Energy

Format Item 9 from the Environmental Assessment for FCN 85 (Dated July 24, 2000, and submitted by Keller & Heckman LLP on behalf of the Notifier: Coalition on PET Safety) is incorporated into this EA by reference.

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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 copolyesters. 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 Notification. The alternative of not clearing 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 subject PET copolyesters 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 subject copolyesters as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

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1803 Building, Midland, MI 48674,

13. Certification

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

Date: October 8, 2003



Lori S. Lickly

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