

Environmental Assessment

1. **Date** [November 22, 2005]
2. **Name of Applicants/Notifiers** Kureha Corporation
Tokyo, Japan
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4147.
4. **Description of the Proposed Action**

The action requested in this Notification is to establish the clearance of the food-contact substance (FCS), polyglycolic acid (PGA), for use as the non food-contact layer, having a maximum thickness of 28 μm , of multi-layer bottles otherwise comprised of polyethylene terephthalate (PET) that will package non-fatty foods (Food Types I, II, IVB, VIA, VIB, VIC (up to 15% alcohol), VIIB, and VIII, as defined at 21 C.F.R. Section 176.170(c), Table 1) under Conditions of Use C through G as defined at 21 C.F.R. Section 176.170(c), Table 2. The FCS will be separated from food by one or more layers of polyethylene terephthalate (PET) that are permitted for this use; the PET food-contact layer(s) will have a total thickness not less than 90 μm .

The subject polymer offers several technical properties that make it useful in a variety of food, pharmaceutical, and medical device packaging applications. In particular, the polymer is an excellent oxygen and carbon dioxide barrier at both low and high relative humidity conditions, and is a very good water vapor barrier. The polymers also offer good clarity.

The Notifier does not intend to produce finished food packaging articles from PGA employing the subject copolymer. Primarily, PGA will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles 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 79% of the materials being deposited in land disposal sites, and about 21% combusted.¹

¹ *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency, Washington DC, 20460, October 2003.

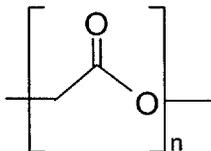
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The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances with respect to the environment surrounding either the use or disposal of food-contact materials prepared from the PGA.

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

The substance that is the subject of this Notification is polyglycolic acid. Its Chemical Abstracts Service Registry Number (CASRN) is 26124-68-5, and its CAS Index Name is "acetic acid, hydroxyl-, homopolymer." It has the following structural formula:



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. In this regard, 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 PGA. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the intended use of the subject polymer to fabricate food packaging materials. In these applications, the polymer 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 non hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced using PGA will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject polymer consists of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymer.

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With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2001 was 229.2 million tons. After materials

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recovery, the total amount of MSW disposed of in 2001 was 161.2 million tons. Of this amount, 33.6 million tons were combusted.² The subject copolymer is composed of carbon, hydrogen, and oxygen, all of which are elements commonly found in municipal solid waste (MSW). The complete combustion of the subject copolymers will produce carbon dioxide and water. The market volume estimate of the subject copolymers to manufacture food-contact articles is a small fraction of the total MSW generated and disposed of in the United States. Accordingly, adding to the waste that is combusted will not significantly alter the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of the subject copolymers will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, *i.e.*, 40 C.F.R. Part 60.

Only extremely small amounts, if any, of constituents of the subject polymer 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. (*See* 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 appropriate corrective action. The anticipated lack of any leaching is especially supported by the fact that the subject polymer is a high molecular weight polymer that contains only minute levels of extractable material, even under conditions that greatly exaggerate environmental exposure conditions.³

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 PGA. The polymer is of relatively high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with PGA.

² *Municipal Solid Waste in the United States: 2001 Facts and Figures*, EPA530-S-03-001, United States Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

³ This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. As shown there, when a representative sample of multilayer PET bottles employing PGA as the non food-contact layers was extracted with 10% ethanol at 66°C for 2 hours followed by 40°C for 30 days, no detectable levels of components of the subject polymer were found in the extracts, using detection limits ranging from 29 parts per billion (ppb) to 34 ppb. Thus, the quantity of leachate from the subject polymer in solid waste deposited in landfills will be extremely small.

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

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 polymer. In particular, the low production of the subject PGA used in food-contact applications, as indicated in confidential sections of this Notification, is not expected to result in significant introductions of landfill leachate. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the subject polymer.

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 PGA used in the manufacture of articles intended for 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. As discussed in Section III.A of the Notification, none of the potential migrating components of the polymers present any toxicological concern at the minute levels at which each 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 PGA. In addition, the use and disposal of articles containing PGA 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 pertains to municipal solid waste combustors and Part 258 that pertains to landfills.

9. Use of Resources and Energy

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As is the case with other food packaging materials, the production, use, and disposal of PGA involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject PGA in the fabrication of food-contact articles is not expected to

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result in a net increase in the use of energy and resources, since PET articles containing PGA are intended to be used in place of containers also manufactured from polymers now on the market for use in food packaging applications. The replacement of these types of materials by PET articles containing PGA is not expected to have any adverse impact on the use of energy and resources. Manufacture of PGA and subsequent conversion of PGA to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of other polymers, such as PET alone. Consequently, the use of PGA employing the subject copolymer will not have an impact on current or future recycling programs.

Regarding recycling, representative PET articles containing PGA have been tested for potential environmental impact on post consumer plastics/PET recycling streams. The test protocol used to assess the potential environmental impact of multilayer PGA bottles was established by the Association of Post-Consumer Plastic Recyclers (APR). The most critical aspects of those tests focus on the potential impact on the bottle-to-bottle end use applications. Therefore, tests were conducted to assess the impact on these more critical applications. A copy of this report is located in a confidential attachment to this Notification, as it contains confidential information.

In these tests, three critical parameters were chosen to establish a potential impact of the PGA barrier on bottle-to-bottle applications; namely, color, haze and intrinsic viscosity. The determination of color is based on measuring the "Lab" values based on the Hunter color system. The L value is a reflection of the luminosity, the a value is a measure of the degree of redness, and the b value represents the degree of yellowness of the sample. Of these three parameters, typically the L and b values are the two most significant. A decrease in the L value causes a darkening in the material. An increase in the b value causes the material to take on a yellowish to brown color. Therefore, these are the two most critical values in bottle-to-bottle or sheet type applications when evaluating colorless transparent materials. In fiber applications, however, a color shift in the Lab values has little impact, as the material is typically dyed to get the desired color. The intrinsic viscosity (IV) can become critical for applications where higher molecular weight (IV) is required, such as in bottle or strapping. If there is an impact on the PET feed stream that decreases the ability of the material to be solid state polymerized (SSP) under normal conditions of time or final IV, then that application may potentially be affected. In conducting the test, three 12 ounce bottle variables were tested under the identical conditions; namely, (1) virgin non-barrier multilayer bottles, (2) multilayer 3% PGA/PET barrier bottles, and (3) multilayer 5% PGA/PET barrier bottles.

The primary function of the polyglycolic acid is to act as a gas barrier. The intended use will be for small bottles where the carbonation loss is greatest. Due to this limited use application, bottles containing PGA will only impact a small portion of the PET feed stream, since these applications tend to be in the "on the go" channel markets which have a significantly lower collection rate.

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In order to assess worst-case scenarios, testing was accomplished at both 50% and 100% bale spiking levels. The materials are subjected to processing representing commercial practices. The specific processing included washing under a given set of conditions representing typical

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PET recycling wash conditions as established by the National Association for PET Container Resources (NAPCOR) protocol, drying, extrusion and solid state polymerization.

The resulting solid-stated polymerization PET pellets were then blended with virgin PET up to a maximum use level of 50%. The critical values were then checked for the resulting material. The findings were as follows:

1. Multilayer bottles with 5% PGA barrier showed no effect on color versus the control. Color differences on the 2 mm strips are negligible for all test conditions.
2. Multilayer bottles with 5% PGA barrier showed no effect on haze. None of the test conditions showed any increase and haze as a result of residual PGA.
3. Solid-stated pellets with 100% content of 5% multilayer PGA bottles showed no changes in color versus the control.
4. Residual PGA does not appear to have a significant effect on solid-state polymerization in either time required or ability to achieve the desired IV.

Based on these test results, it was concluded that there would be no significant impact on the current PET recycle feed streams by introduction of up to 5% PGA content in multilayer PET bottles even if these bottles became a significant portion of the PET feed stream.

Therefore, for all of the foregoing reasons, the use of PGA as described in this Notification will not have an adverse impact on energy and resources.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles containing PGA. 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; the use of renewable resources for the manufacture of PGA; and the lack of impact on the PET recycling stream of the use of PGA as an interior layer with PET to produce finished food-contact articles. Thus, the use of the subject PGA 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

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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 PGA

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excellent qualities of PGA 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 polymer as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

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

Date: [November 22, 2005]



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