

# Environmental Assessment

**1. Date** January 26, 2012

**2. Name of Applicant / Submitter** ADEKA Corporation

**3. Address** ADEKA Corporation  
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All communications on this matter are to be sent in care of Agent for Notifier

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## 4. Description of Proposed Action

The action requested in this notification is the establishment of a clearance for the food contact substance (FCS) 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt to be used in polyethylene phthalate polymers (PET) according to 21 CFR 177.1630. The polymers will contain not more than 0.1% of the FCS. However, as the FCS becomes covalently bound to the PET polymer this modified PET polymer becomes the food additive. The clearance established by this notification would permit the use of the FCS and of the modified PET polymer in contact with all types of food according to 21 CFR 177.1630 for PET polymers.

The notifier does not intend to produce finished food packaging materials or articles from the subject PET polymers. Rather, the FCS will be sold to compounders of polymers and the modified PET polymer will be sold to manufacturers engaged in the production of food contact articles. Food contact articles produced with the modified PET 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 of the modified PET polymer will occur nationwide, with the material being land disposed, combusted, or recycled. According to the US Environmental Protection Agency's (EPA) 2010 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 11.9% was combusted, and 33.8% was recovered for recycling including 8.6% being composted<sup>1)</sup>.

The types of environments present at and adjacent to the 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 made from the modified PET polymer.

## **5. Identification of Substance that is the Subject of the Proposed Action**

The food contact substance (FCS) that is subject of this notification is 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt. The FCS is added at a maximum concentration of 0.1% to PET polymers described in 21 CFR 177.1630 and is covalently bound to the PET polymer. The modified PET polymer has to be regarded as the food additive in this Environmental Assessment.

The modified PET polymer is a polyester like PET polymers described in 21 CFR 177.1630. The molecular weight distribution and the level of oligomers with molecular weight below 1000 Dalton do not differ significantly between PET polymer without the FCS and the modified PET polymer containing the FCS.

## **6. Introduction of Substances into the Environment**

Under 21 CFR 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 modified PET 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 copolymers to fabricate packaging materials. In these applications, the copolymers 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.

Food packaging materials produced from modified PET polymers will be used nationwide. Food contact articles produced from the polymers are expected to be disposed of by the ultimate consumer in patterns similar to the current disposal of containers made from PET polymers that are chemically identical to the polymers covered by this notification. Bottles fabricated from the subject modified PET polymers are expected to bear the resin identification code used for PET containers and are expected to be disposed of similarly to conventional PET.



Thus, in keeping with established disposal patterns for PET bottles and jars, it is expected that about 28% of bottles and jars prepared from PET polymers will be recycled<sup>1)</sup>. The remaining containers are expected to be disposed of in accordance with usual solid waste disposal patterns; thus, about 82% of the solid waste not recycled or composted will be disposed of by means of landfill and 18% will be incinerated<sup>1)</sup>.

Only extremely small amounts, if any, of the modified PET polymer constituents are expected to enter the environment as a result of the landfill disposal of food contact articles, in light of Environmental Protection Agency's (EPA) regulations governing municipal solid waste (MSW) landfills. EPA's regulations require new MSW 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 CFR 258. Although owners and operators of existing active MSW landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor ground water and to take corrective action as appropriate.

The subject modified PET polymers consist of carbon, hydrogen, oxygen, and nitrogen. Combustion products are expected to be carbon dioxide, water, nitrogen oxides, the latter reflecting the small amounts of the nitrogen containing FCS used as modifier/nucleating agent in conventional PET polymers. Thus, no toxic combustion products are expected as a result of the proper incineration of the polymers.

## **7. Fate of Emitted Substances in the Environment**

### **(a) Air**

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the modified PET polymers. 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 polymers largely are carbon dioxide and water, along with small quantities of nitrogen oxides. 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 (the actual concentration of the nitrogen containing FCS in the modified PET polymer amounts to 0.1% at maximum).

### **(b) Water**

No significant effects on the concentrations of and exposure to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject polymers. No significant quantities of any substance will be added to these water systems upon proper incineration of the polymers, nor upon their disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

### **(c) Land**

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 polymers. In particular, the extremely low levels of aqueous migration of polymer components indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food contact articles are disposed of. Furthermore, the low production of modified PET polymers for use in food contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

Considering the foregoing, there is no reasonable expectation of a significant impact on the environment due to the proposed use of modified PET polymers 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 subject polymers consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effects on organisms in the environment are expected as a result of the disposal of food contact articles made from the subject polymers. Therefore, the use and disposal of the subject polymers in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g. EPA's regulations in 40 CFR 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 modified PET polymers involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymers 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 polymers are intended to be used in place of materials now on the market for use in packaging applications. Polymers currently used in such applications include, but are not limited to, PET polymers cleared under 21 CFR 177.1630.

The partial replacement of other polymers by modified PET polymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymers and their conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace.



Food contact articles prepared from the subject modified PET polymers are expected to be recycled along with other PET containers. The subject modified PET polymers are intended as replacement for polymers that are already cleared under an applicable food additive regulation (21 CFR 177.1630). Because the polymers that are subject to this notification do not differ from other regulated PET polymers, the presence of the subject modified PET polymers in post-consumer PET recycle streams will have no adverse impact on the recycling of these materials. This being the case, the containers are expected to bear the PET resin identification code to facilitate post-consumer collection, as do PET containers currently produced. Modified PET polymer containers will be included in the same post-consumer stream as other PET polymer bottles and will be processed and sent into appropriate recycle markets with existing collection programs from recycled PET since the notified modified PET polymer will be indistinguishable from the currently recycled PET resins.

For the foregoing reasons, the notifier respectfully submits that the proposed use of the FCS to produce modified PET polymers will have no significant adverse impact on current or future recycling programs for post-consumer PET.

#### **10. Mitigation Measure**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact materials made from the subject polymers. This is primarily due to the minute levels of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products of the polymers, and the close similarity of the subject polymers to the materials they are intended to replace. Thus, the use of the subject polymers 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 approving the action proposed herein would simply result in the continued use of the materials which the subject polymers would otherwise replace. Such action would have no environmental impact.

In view of 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 consequent absence of any significant environmental impact which would result from their use, the establishment of an effective Food Contact Notification to permit the use of the FCS to manufacture modified PET polymers as described herein is environmentally safe in every respect.

## 12. List of Preparers

Dr. Andreas Tschech, WTConsulting GmbH, Weierweg 7, 4410 Liestal, Switzerland.

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



January 26, 2012

Dr. Andreas Tschech

WTConsulting GmbH

On behalf of ADEKA Corporation

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- 1) Municipal Solid Waste in the United States: 2009 Facts and Figures; EPA 530-R-10-012, US Environmental Protection Agency, December 2010