

## Attachment 8

# Environmental Assessment

**1. Date** June 20, 2008

**2. Name of Applicant / Submitter** BASF SE

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#### 4. Description of Proposed Action

The action requested in this notification is the establishment of a clearance to permit the use of styrene, methyl methacrylate, and glycidyl methacrylate copolymer as a polymeric chain extender at a maximum level of 0.4% by weight in all polyesters. Polyesters employing the subject copolymer are intended for use as food contact articles in contact with all types of food (except food containing more than 15% alcohol) under conditions of use E through G as defined at 21 CFR 176.170(c), Table 2.

Use of the subject copolymer in polyesters increases the molecular weight of the polyesters offering several technical properties that make them useful in a variety of food contact applications. In particular, the copolymer is used to address the molecular weight degradation that occurs in PET during recycling.

The notifier does not intend to produce finished food packaging materials from polyesters employing the subject copolymer. Primarily, polyesters employing the copolymer will be sold to manufacturers engaged in the production of food contact materials. Food contact materials produced with the use of such modified polyesters 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; according to the US Environmental Protection Agency's (EPA) 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling including 8.4% being composted<sup>1</sup>.

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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 regarding the environment surrounding either the use or disposal of food contact materials prepared from polyesters employing the copolymer.

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

The substance that is the subject of this notification is a copolymer of styrene (CAS No. 100-42-5), methyl methacrylate (CAS No. 80-62-6), and glycidyl methacrylate (CAS No. 106-91-2).

#### **6. Introduction of Substance 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 the subject styrene/methyl methacrylate/glycidyl methacrylate copolymer. 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 copolymer with polyesters employing the copolymer used 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 waste in accordance with established procedures.

Disposal by the ultimate consumer of polyesters employing the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill and incineration. The subject copolymer, as well as polyesters, consists of carbon, oxygen and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2005 was 245.7 million tons. After materials recovery, the total amount of MSW disposed of in 2005 was 166.7 million tons. Of this amount, 33.4 million tons were combusted. The subject copolymer is composed of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste. The complete combustion of subject copolymer will produce carbon dioxide and water. Because the market volume estimate of subject copolymer to manufacture food contact articles is a small fraction of the total MSW generated and disposed of in the United States and because the subject copolymers will replace and compete with similar materials (see Item 9 below), adding to the waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts

currently generated by municipal waste combustors, it is not expected that the combustion of the subject copolymer will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e. 40 CFR 60.

Only extremely small amounts, if any, of constituents of the subject copolymer are expected to enter the environment as a result of the landfill disposal of food contact articles, in light of EPA's regulations governing municipal solid waste landfills. EPA's regulations require new municipal 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 lack of any significant introduction of substances into the environment also is supported by data showing the compostability of articles (biodegradable polyesters) made with the subject copolymer. These data are confidential to the submitter and are contained in an appendix to the cover letter filed with the Environmental Assessment to FCN 594.

## **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 copolymer in polyesters. The copolymer 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 polyesters employing the copolymer.

The products of complete combustion of the copolymer would be 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 the manufacture of polyesters.

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

As noted above in Section 6 of this EA, data showing the compostability of articles made with the subject copolymer are contained in a separate confidential appendix to the EA of FCN 594. The compost generated showed no ecotoxicity.

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 copolymer. In particular, the low production of the subject copolymer for use in polyesters used in food contact applications, as indicated in confidential

sections of this notification, is not expected to result in significant introductions of landfill leachate. Finally, the presence of biodegradable polyesters employing the subject copolymer in controlled commercial composting sites is not anticipated to result in introduction of adverse substances into terrestrial ecosystems. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of subject copolymer.

Considering the foregoing, there is no reasonable expectation of a significant impact on the environment due to the proposed use the subject copolymer in the manufacture of polyester 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 use of polyesters employing the subject copolymer consist of extremely small quantities of combustion products, extractables, and the products of commercial composting. As discussed in Part III of the notification, none of the potential migrating components of the copolymer present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effects on organisms in the environment are expected as a result of the disposal of food contact articles made of polyesters employing the subject copolymer. In addition, the use and disposal of food contact articles made of polyesters employing the subject copolymer 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. Finally, biodegradable polyesters employing the subject copolymer exhibited complete disintegration under controlled commercial composting conditions and the compost generated indicated no adverse ecotoxicity.

#### **9. Use of Resources and Energy**

As is the case with other food packaging materials, the production, use, and disposal of polyesters employing the subject copolymer involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymer in polyesters used in the fabrication of food contact materials is not expected to result in a net increase in the use of energy and resources, since polyesters employing the subject copolymer are intended to be used in place of similar polyesters now on the market for use in packaging applications.

Polymers currently used in the applications in which the subject copolymer is anticipated to be used include polyethylene terephthalate (PET). The subject copolymer will be used as chain extender, e.g. in recycling of PET, to maintain the physical properties of recycled PET. In Attachment 2 of the FCN more details on the physical properties of recycled PET containing the subject copolymer are provided. Recycling of PET will save natural resources such as petroleum products.

The use of the subject copolymer in recycled PET or other polyesters is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer, its use in polyesters, and subsequent conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of polyesters employing e.g. other chain extenders.

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

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact articles made from polyesters employing the subject copolymer. This is primarily due to the minute levels of leaching of potential migrants from the finished article and secondly to the insignificant impact on environmental concentrations of combustion products of the copolymer. Thus, the use of the subject copolymer in polyesters 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 currently used in the manufacture of food contact articles made of polyesters. Such action would have no environmental impact or with regard to saving of natural resources, e.g. petroleum products, when using recycled PET would have a negative effect. In view of the excellent qualities of polyesters employing the subject copolymer 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 copolymer in polyesters 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/her knowledge

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- 1) Municipal Solid Waste in the United States: 2005 Facts and Figures; EPA 530-R-06-011, US Environmental Protection Agency, Washington DC, 20460, October 2006.