

Attachment 9 - Environmental Assessment

1. **Date** October 17, 2007

2. **Name of Applicant/Notifier** BASF Aktiengesellschaft

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4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for 1,4-benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, and hexamethylene diisocyanate (HMDI) as a single use food packaging material. The purpose of the Notification is to permit the use of the subject polymer for use as a film or coating having a maximum thickness of 4.7 mils (120 microns (μm)), with an average thickness of 2 mils (51 μm), to fabricate food-contact articles in contact with all food types under Conditions of Use C through G. Examples of food packaging materials that may be made from the food-contact substance include, but are not limited to, garbage bags intended for composting, coatings used on clamshell containers intended for use in serving food, and stand-alone films for use as food wraps.

The Notifier intends to produce finished food packaging materials from the subject polyester. Food-contact materials produced with the polyester in the United States 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 76% of the materials being deposited in land disposal sites, and about 24% combusted.¹ While Ecoflex is compostable, this is not expected to be a significant means of disposal in the United States because composting is not currently a significant waste disposal method in this country.

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 made from the subject polyester.

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

The food-contact substance that is the subject of this Notification is 1,4-benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, and HMDI, *i.e.*, a copolyester produced from dimethyl terephthalate, adipic acid, 1,4-butanediol, and HMDI. The polymer is a polyester derived from diols and diacids or dimethyl esters. Thus, the structure is one in which the polymer backbone consists of alternating units derived from diols and acids/esters. HMDI is added in small quantities (<1%) as a chain extension agent. The material's tradename is Ecoflex.

Finally, the M_w and M_n for the substance are approximately 137,000 Daltons and 36,000 Daltons, respectively, for a M_w/M_n of approximately 3.81.

¹ *Characterization of Municipal Solid Waste in the United States 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998

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. 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 Ecoflex copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements are not provided here.

No environmental release is expected upon the use of the subject polymer to fabricate packaging materials. In these applications, the polymer is expected to be used as the film and as a coating, and 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.

Disposal by the ultimate consumer of food-contact materials produced by the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. Disposal by composting in the U.S. is not expected to be significant; thus, we do not anticipate any significant introduction of substances into the environment as a result of composting.

If the material is introduced into commercial compost sites, the polymer will degrade into smaller polymeric components and ultimately, to carbon dioxide and water. Biodegradability testing has been undertaken in accordance with German Standard DIN V 54900 (1998),² which is equivalent to the European Standard EN 13432, and virtually identical to the American

² DIN CERTO Gesellschaft für Konformitätsbewertung mbH is the certification organization of DIN, the German Institutes for Standardization.

Society for Testing and Materials (ASTM) standard D6400. A copy of ASTM D6400 is included as an attachment to this Environmental Assessment. The certification by DIN CERTCO Gesellschaft für Konformitätsbewertung mbH also is included in an attachment to this Environmental Assessment.

The subject polymer was tested in a controlled composting test in accordance with ISO 14855, which is described in DIN V 54900. The process may take 180 days in a controlled compost test operated at 136°F (58°C) under aerobic conditions. Using cellulose as a reference standard, the subject polymer fulfilled the requirements of ASTM D6400 by reaching a relative biodegradation above 90% relative to cellulose in 80 days. Furthermore, a film sample of the subject polymer, 120 µm (or approximately 4.7 mils (0.0047 inch)) thick, was tested for disintegration in a pilot-scale composting test in accordance with ASTM D6400 and EN 13432. The sample met the requirements of ASTM D6400 and EN 13432, as the film had disintegrated sufficiently in 6 weeks, *i.e.*, at least 90% of the film was converted into pieces less than 1-5 mm².

The compost generated in the disintegration test was subjected to ecotoxicity testing by Geschäftsbereich PlanCoTec, INFU mbH Ingenieurgesellschaft für Umweltplanung and BASF Aktiengesellschaft, according to OECD Guideline for Testing of Chemicals No. 208: "Terrestrial Plants, Growth Test," and OECD Guideline for Testing of Chemicals No. 207: "Earthworm, Acute Toxicity Tests," respectively. A copy of both OECD Guidelines and respective test results are included as an attachment to this Environmental Assessment. In sum, no adverse ecotoxicity was observed in germination and growth of wheat, mustard, mung bean, and summer barley. In addition, the percentage survival of earthworms in the test compost/artificial soil mixtures was equal to the survival in blank compost/artificial soil mixtures.

The subject polymer consists of carbon, hydrogen, oxygen, and nitrogen. Combustion products are expected to be carbon dioxide, water, and nitrates, the latter reflecting the small

amounts of HMDI as a chain extending agent. (See Form 3480 page 4). Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of 1,4-butanediol, adipic acid, dimethyl terephthalate or terephthalic acid constituents 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 groundwater monitoring systems. 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 corrective action as appropriate.

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 Ecoflex copolymer. The polymer is of 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 these polymers.

The products of complete combustion of the polymer largely 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 polymer in the amounts utilized for food packaging applications.

(b) Water

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 the polymer, nor upon its 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 copolymer. In particular, the low levels of migration of components of dimethyl terephthalate/terephthalic acid, and 1,4-butanediol, demonstrated by theoretical calculations, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. (Adipic acid migration was not estimated because it is Generally Recognized as Safe (GRAS) under 21 C.F.R. § 184.1009). Furthermore, the very low production of Ecoflex copolymers for use in food-contact applications minimizes 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.

As noted above in Section 6 of this Environmental Assessment, the subject polymer exhibited sufficient disintegration at the end of 6 weeks under controlled composting conditions. The compost generated in the disintegration test was subjected to ecotoxicity testing; no adverse ecotoxicity was observed in germination and growth of wheat, mustard, mung bean, and summer barley, and no adverse ecotoxicity was observed in the survival of earthworms.

Considering the foregoing, there is no reasonable expectation of a significant impact on the environment due to the proposed use of Ecoflex copolymers 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 use of the subject polymer consist of extremely small quantities of combustion products and extractables. As discussed in Part III of the Notification, the polymer is safe when used as intended. Furthermore, none of the monomers used in the manufacture of the polymers is considered to be a carcinogen.

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the polymer. In addition, the use and disposal of the polymer are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors and in Part 258 that pertain to landfills. Finally, the subject polymer exhibited sufficient disintegration under controlled composting conditions and the compost generated indicated no adverse ecotoxicity, if such composting were to occur. The ecotoxicity testing conducted on this substance is summarized in an attachment to this Environmental Assessment, as previously noted.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of Ecoflex copolymers involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer as a coating and as a film is not expected to result in a net increase in the use of energy and resources, since the copolymer could be used in

materials which will be used in place of materials now on the market for use in food-contact articles where particular packaging advantages, such as clarity, are desired. However, due to its cost relative to other polymers, Ecoflex is only likely to be used for specific applications requiring compostability. Projected production volume reflects this reality, and is only expected to reach a specific limit in the U S by 2010.³ Specifically, as discussed in Item 4 above, the proposed use in this Notification for the subject polymer is as a coating and as a film to fabricate food-contact articles. It should be noted that copolymers of adipic acid, dimethylterephthalate, and 1,4-butanediol are already cleared for use in coatings under 21 C.F.R. § 175.300.

The partial replacement of other polymers by Ecoflex copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers. Moreover, substances similar to the substance that is the subject of this Notification currently in use for food packaging are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration; bottles, the type of container that is recovered for recycling to a significant extent, are not covered by this Notification. In this country, packaging materials produced from Ecoflex copolymers are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

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 polymer. This is primarily due to the minute levels of leaching of potential migrants from the finished article and

³ See Confidential Attachment 15 .

the insignificant impact on environmental concentrations of combustion products of the polymer. Thus, the use of the polymer 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 polymer 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 its use, the establishment of an effective Food Contact Notification to permit the use of Ecoflex copolymers as described herein is environmentally safe in every respect.

12. List of Preparers

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

Date: October 17, 2007

Dr. Sabine Vogt, Manager Product Safety and Regulatory Affairs

ATTACHMENTS

- ASTM Standard D 6400.....Attachment 9 a.
- DIN: Notification of Registration.....Attachment 9.b.
- OECD Guideline for Testing of Chemicals: 207.....Attachment 9.c.
- OECD Guideline for Testing of Chemicals: 208.....Attachment 9.d.
- Ecoflex Compostability Testing: Earthworms.... .Attachment 9.e.
- Projected Production Volume – **CONFIDENTIAL**.....Attachment 15