

**ENVIRONMENTAL ASSESSMENT  
SUNOCO FOOD CONTACT NOTIFICATION**

1. **Date:** October 13, 2004
2. **Name of Applicant/Notifier:** Sunoco Inc. (R&M)
3. **Address:** Technology & Commercial Center  
550 Technology Drive  
Pittsburgh, Pennsylvania 15219

All communications on this matter are to be sent in care of Counsel for Notifier:  
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4. **Description of the Proposed Action**

The action requested in this notification is to establish the clearance of the food-contact substance (FCS), which is described as a blend of polypropylene (PP) homopolymer with ethylene/propylene (E/P) bipolymer. The FCS may be used in contact with all food types under Conditions of Use A through H, as set forth in Tables 1 and 2, respectively, of 21 C.F.R. §176.170(c).

The subject blend offers several technical properties that make it useful in a variety of food packaging applications. In particular, the FCS provides excellent impact properties.

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The Notifier does not intend to produce finished food packaging from the subject bipolymer blends. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the FCS 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.<sup>1</sup>

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 the bipolymer blends.

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

The FCS that is the subject of this Notification is the blend of PP homopolymer with E/P bipolymer. The FCS will be marketed as either Sunoco Chemicals' 4000, 5000, 6000, or 9000 series polypropylene.

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

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<sup>1</sup> *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.

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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 bipolymer blends. 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 bipolymer blends to fabricate packaging materials. In these applications, the bipolymer blends are expected to be used as the basic polymer to fabricate all forms of food-contact articles, and will be entirely incorporated into the finished food-contact article. 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 articles produced by the subject bipolymer blends will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The bipolymer blends consist primarily of carbon and hydrogen, with some of them containing small amounts of oxygen and nitrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the bipolymer blends.

Only extremely small amounts, if any, of the bipolymer blend 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

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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 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. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>2</sup>

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 bipolymer blends. 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 the bipolymer blends.

The products of complete combustion of the bipolymer blends would be carbon dioxide and water, along with small amounts of nitrogen oxides; the concentrations of these substances

<sup>2</sup> This expectation is confirmed by the results of extraction studies described in this FCN. As shown herein, when several different grades of the bipolymer blends were extracted with either 10% ethanol or 95% ethanol at 121°C for 2 hours followed by 40°C for 10 days, minute levels of components of the subject bipolymer blends were found in the extracts at levels ranging from 0 mg/in<sup>2</sup> to a maximum of 0.978 mg/in<sup>2</sup>. These levels are generally lower than the levels extracted from the cleared PP; 0 mg/in<sup>2</sup> to a maximum of 1.149 mg/in<sup>2</sup>. Thus, the quantity of leachate from the bipolymer blends in solid waste deposited in landfills will be extremely small, and certainly less than from PP currently used and disposed.

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in the environment will not be significantly altered by the proper incineration of the polymers 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 bipolymer blends. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, 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 bipolymer blends. In particular, the extremely low levels of maximum migration of components of the bipolymer blends, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the bipolymer blends.

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

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proposed use of the bipolymer blends 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 bipolymer blends consist of extremely small quantities of combustion products and extractables. The monomers from which the FCS is manufactured are not considered to present a substantive genotoxicity or carcinogenicity risk at the minute levels at which they may enter the diet. Furthermore, it is generally recognized that oligomeric substances are of lower potential toxicity than the monomers from which they are produced. Consequently, based on the absence of any concern vis-à-vis the monomers, the oligomers also are not expected to present any toxicological concern. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the bipolymer blends. In addition, the use and disposal of the bipolymer blends 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 pertain to municipal solid waste combustors, and Part 258 that pertain 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 the bipolymer blends involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject bipolymer blends 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 bipolymer blends are intended to be used in packaging that will be used in place of similar materials now on the market for use in food packaging applications.

The partial replacement of these types of materials by the bipolymer blends is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers. Articles fabricated from the subject FCS will be disposed of by means of sanitary landfill and incineration. Packaging materials produced from the FCS 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 FCS. 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 bipolymer

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blends, and the insignificant impact on the use of resources and energy when compared with the materials they are intended to replace. Thus, the use of the FCS 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 that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace; such action would have no environmental impact. In view of the fact that the bipolymer blend 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 establishment of an effective Food Contact Notification to permit the use of the subject bipolymer blends as described herein is environmentally safe in every respect.

12. **List of Preparers**

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**13. Certification**

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

Date: 12/14/04



Joan Sylvain Baughan  
Counsel for Sunoco Chemicals

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