

**Attachment VI**  
**Environmental**  
**Assessment**

- 1. Date:** March, 03, 2005
- 2. Name of Notifier:** BASF AG
- 3. Address:** All communications on this matter are to be sent to BASF AG  
Dr. Martin Klatt, KS/KS – E 100, D-67056 Ludwigshafen,  
Germany

**4. Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of nylon 6/66 (caprolactam-hexamethylenediamine-adipic acid copolymer) in the manufacture of films, up to 1 mil (0.001 inch) in thickness, in contact with all types of food under all conditions of use. The Notifier does not intend to produce finished food packaging materials from the subject nylon 6/66 polymers. Rather, the Notifier plans to produce both resin and film products from the nylon 6/66, which, in turn, will be sold to manufacturers engaged in the production of food-contact films. Food-contact films produced with the use of the polymers 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<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 films prepared from nylon 6/66 polymers.

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

The food-contact substances that are the subject of this Notification are copolymers of caprolactam (hexahydro-2H-azepin-2-one), hexamethylenediamine (1,6-hexanediamine), and adipic acid (hexanedioic acid), which have a Chemical Abstract Service (CAS) Registry Number of 24993-04-2 and a CAS Registry Name of Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine.

<sup>1</sup> Municipal Solid Waste in the United States: 2001 Final Report, EPA 530-S-03-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

A confidential description of the polymers appears in Section II-A of this Notification.

## 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 nylon 6/66 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 polymers to fabricate packaging films. In these applications, the polymers 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 copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymers consist of carbon, oxygen, hydrogen, and nitrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers. Only extremely small amounts, if any, of nylon 6/66 polymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact films, 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. 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 collection 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>

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<sup>2</sup> This expectation is confirmed by the results of worst-case migration calculations based on an assumption 100% migration of the nylon 6/66 components, as described in part II - section F of the Notification. As shown there, calculations based 100% migration of the components of the nylon 6/66 films give levels ranging from 180 parts per billion (ppb) to 6.4 parts per million (ppm). Thus, the quantity of nylon 6/66 constituents in solid waste deposited in landfills will be extremely small.

## 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 nylon 6/66 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 films manufactured with these polymers. The products of complete combustion of the polymer would be carbon dioxide and water, along with small amounts 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. 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 copolymers. 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 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 nylon 6/66 polymers. In particular, the extremely low levels of migration of components of the polymer, even assuming 100% migration, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact films are disposed of. Furthermore, the very low production of nylon 6/66 polymers for use in food-contact applications, as indicated in Attachment 1 of this Notification. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

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 nylon 6/66 polymers in the manufacture of films 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 polymers consist of extremely small quantities of combustion products and extractables. As discussed in Section II-G of the Notification, none of the potential migrating components of the polymers present any toxicological concern at the minute levels at which they 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 films containing the copolymers. In addition, the use and disposal of the copolymers 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**

As is the case with other food packaging materials, the production, use and disposal of nylon 6/66 polymers involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers 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 copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications. Polymers currently used in the applications in which nylon 6/66 polymers are anticipated to be used include other nylon resins that are permitted for the same use in food-contact films as proposed in this Notification for nylon 6/66, such as biaxially oriented nylon 6, biaxially oriented nylon 66, and biaxially oriented PET films. The replacement of these types of materials by nylon 6/66 is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging films will consume energy and resources in amounts comparable to the manufacture and use of biaxially oriented nylon 6 and nylon 66, both of which are currently permitted for use in the applications that will be covered by this Notification becoming effective. Moreover, nylon 6/66 polymers will be used to manufacture films only. Consequently, nylon 6/66 polymers are not anticipated for use in the manufacture of bottles used for packaging milk or soda; packaging for other types of food, especially films, are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from nylon 6/66 polymers 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 films fabricated from the subject polymers. This is primarily due to the minute levels of leaching of potential migrants from the finished film, the insignificant impact on environmental concentrations of combustion products of the polymers, and the close similarity of the subject copolymers to the materials they are intended to replace. Thus, the use of the copolymers 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 copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the nylon 6/66 polymers 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 films, and the absence of any significant environmental impact which would result from their use, the clearance of the use of nylon 6/66 polymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

**12. List of Preparers**

- a. Dr. Martin Klatt, Head of Product Safety and Regulatory Affairs, BASF AG, D-67056 Ludwigshafen
- b. Dr. Uwe Blumenstein, Manager Product Safety and Regulatory Affairs, BASF AG, D-67056 Ludwigshafen

**13. Certification**

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

Date: 03.03.05

