

**G. Environmental Assessment**

- 1. Date** June 11, 2002
  
- 2. Name of Applicant/Notifier** EMS Chemie
  
- 3. Address** All communications on this matter are to be sent in care of Counsel for Notifier, Ralph A. Simmons, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.  
  
Telephone: (202) 434-4120.

**4. Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the expanded use of nylon **6/69** resin to cover the polymer with water extracts up to 6% as a non-food contact layer of multilayer films used in contact with food. The polymer that is the subject of this notification is marketed under the name **Although Nylon 6/69** resins are currently cleared for the intended use in 21 C.F.R. § 177.1500 ("Nylon resins"), the current clearance specifies a water extractables limit of **3%**; the action requested in this Notification is to expand the water extractables limit to **6%**, while leaving all other specifications and limitations unchanged. This water extractables expansion is of interest to EMS Chemie

because the higher extract content in the nylon 6/69 offers better processability for EMS Chemie's customers.

The Notifier does not intend to produce finished food packaging materials from the subject nylon 6/69 resin. Rather, the polymer will be sold to manufacturers engaged in the production of multilayer food-contact films. Food-contact materials produced with the use of the 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 food-contact films containing nylon 6/69 as a component of non-food-contact layers will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.<sup>11</sup> Films containing nylon 6/69 are not expected to be recycled, as discussed under Format Item 9 below.

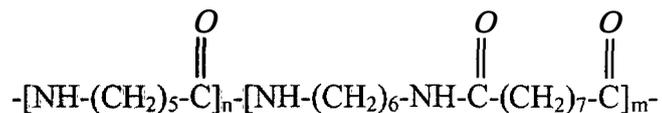
The types of environments present at, and adjacent to, these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from liquid crystalline polymers.

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

The additive that is the subject of this Notification is a copolymer of *epsilon*-caprolactam (hexahydro-2H-azepin-2-one), hexamethylenediamine (1,6-hexanediamine), and azelaic acid

<sup>11</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.

(nonanedioic acid). The 'Chemical Abstract Service (CAS) Registry Number for nylon 6/69 is 51995-62-1. As dealt with by the Notifier, the polymer is marketed under the trade name \_\_\_\_\_ and are referred to herein as such. The chemical structure of nylon 6/69 may be diagrammed as follows,:



A confidential description of nylon 6/69 appears in Section B 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 6/69. 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 polymer to fabricate food-contact films. In these applications, the polymer **will** be entirely incorporated into the

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finished food-contact films and essentially all of it is expected to remain with these materials throughout their use.

Disposal by the ultimate consumer of food-contact materials produced by the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymer consists of carbon, oxygen, hydrogen, and nitrogen. No toxic combustion products are expected as a result of the proper incineration of the polymer.

Based on migration studies performed to demonstrate human safety of the proposed use and reported elsewhere in the **FCN**, we expect only very low levels of the FCS to leach from the multilayer food-contact films containing nylon 6/69. Moreover, even if a very small amount of the FCS migrates from the films in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the regulations of the Environmental Protection Agency (EPA) governing municipal solid waste landfills.<sup>12</sup>

Nylon 6/69 is composed of carbon, hydrogen, oxygen, and nitrogen, which are elements commonly found in municipal waste. The complete combustion of nylon 6/69 in a properly functioning incinerator will produce carbon dioxide, water, and nitrogen oxides. Since the market volume of nylon 6/69 is a small fraction of the municipal solid waste generated and disposed of in the United States, adding it to waste that is combusted will not alter significantly

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The United States Environmental Protection Agency's (EPA) 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. 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 emissions from the municipal waste generators. Due to the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste incinerators, we do not expect that the combustion products from the incineration of nylon 6/69 will violate applicable emissions laws and regulations.

## **7. Fate of Substances Release into the Environment**

No information needs to be provided on the fate of substances released into the environment as the result of use and disposal of multiplayer films containing nylon 6/69 because, as discussed under Format Item 6, only small quantities, if any, will be introduced into the environment from its use and disposal.

## **8. Environmental Effects of Released Substances**

No information needs to be provided on the effects of substances released into the environment as the result of use and disposal of multilayer films containing nylon 6/69 because, as discussed under Format Item 6, only small quantities, if any, will be introduced into the environment from its use and disposal. Therefore, we do not expect the use and disposal of nylon 6/69 to result in significant effects to the environment or to threaten violation of applicable laws and regulations (e.g., EPA's regulations in 40 C.F.R. Parts 60 and 258).

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## 9. Use of Resources and Energy

The consumption of nylon 6/69 for the proposed food-contact use in this Notification will be only a small fraction of the total market volume for nylon used in food-contact material in the United States.

The food-contact substance, nylon 6/69, will be used as a component of food-contact **films** that are expected to compete with and replace other food-contact films composed of **currently** regulated materials. Currently, very few, if any, food-contact films are recycled. **Further**, food-contact films are not likely to be recycled in the future because it is difficult to **clean** films that have residual food adhering to them and because food-contact films are made **from** diverse materials that are not specifically identified on the finished packaging material. **Thus, the** use of nylon **6/69** will not change current recycling patterns and, therefore, it is not expected to significantly affect the use of depletable resources. Also, no significant increase in energy use will result from the proposed action because nylon 6/69 will replace similar materials **that** use **similar** natural resources.

## **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; the insignificant impact on environmental concentrations of combustion products of the polymer; and the close similarity of the subject polymer to the materials they are intended to replace. Thus, the use of the copolymer 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 FCN. 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 excellent qualities of the nylon 6/69 resin for use as the non-food-contact layer of multilayer food-contact films, 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 nylon 6/69 resin 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 his knowledge.

Date: June 11, 2002



**Ralph A. Simmons**

Counsel for EMS Chemie

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